Received: 4 February 2022 | Revised: 5 April 2022 | Accepted: 19 April 2022

DOI: 10.1111/ajt.17065

VIEWPOINT

COVID-19 and transplantation—Data censoring

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During the early wave of the COVID-19 pandemic, the Scientific Registry of Transplant Recipients (SRTR) designated a "black out" period between March 12, 2020, and June 12, 2020, for transplant outcomes reporting. We discuss the implications and potential bias it has introduced as it may selectively favor the outcomes for certain regions and harm other regions due to varied effects of different waves of COVID-19 infections across the United States.

KEYWORDS
editorial/personal viewpoint, ethics and public policy, law/legislation, organ transplantation in general, patient survival, Scientific Registry for Transplant Recipients (SRTR)

1 | INTRODUCTION

Infection with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) causing COVID-19 was declared a pandemic on March 11, 2020. In the United States alone, COVID-19 infection has resulted in nearly 75 million cases to date, with more than 880,000 deaths.[1,2] The resultant strain on health-care systems and socioeconomic conditions worldwide have been profound.[3] High-risk populations, such as organ transplant recipients and immunocompromised individuals, are vulnerable to severe COVID-19 and subsequent morbidity and mortality.

As COVID-19 cases started to surge in the United States—the Scientific Registry of Transplant Recipients (SRTR) chose a data censoring "black hole" period from March 12, 2020 to June 12, 2020, as the immediate effects of the pandemic on transplant recipients were unknown.[4] Patients transplanted prior to March 12, 2020

Abbreviations: CDC, Centers for Disease Control; SRTR, Scientific Registry of Transplant Recipients; UNOS, United Network for Organ Sharing; US, United States; WHO, World Health Organization.

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disappeared into this "black hole" following that date and those transplanted between March 12, 2020, and June 12, 2020, were considered to not exist for the purpose of transplant data metrics and analysis.[4] This period was chosen because it reflected the first wave or peak of COVID-19 infections. At that time, it was unclear how the COVID-19 infection would affect transplant center metrics directly due to changes in transplant center practice and indirectly due to COVID-19 cases in the community.

Several methods were implemented to curtail the pandemic such as contact tracing, lock downs, mask requirements, hand hygiene, and social distancing. Better understanding of the virus and its pathogenesis has led to vaccines and novel therapeutics such as targeted antibody and antiviral therapies. Despite these efforts, the virus continues to circulate in our communities. Several viral variants have emerged in the past 2 years causing "surges/waves" in case numbers and mortality.[5] These "waves" of infection have affected states/geographic regions in the United States with varying timing and magnitude (Figures 1 and 2—graphs generated from Center for Disease Control (CDC) data[2]). Hence, we assert that the period of data censoring chosen by the SRTR has created inequality in measurements and metrics across the transplant centers in the United States.

As shown in Figures 1 and 2—the time between March 12, 2020, and June 12, 2020, coincided with an early wave of COVID-19 that mostly centered in the predominantly densely populated Northeastern part of the country (United Network for Organ Sharing [UNOS] regions 1, 2, 9 [Figure 3]). During this early wave, transplant centers in other parts of the country were not affected to the same extent. Interestingly, the highest COVID-19 infection rates and pandemic mortality were observed between October 2020 and March 2021, essentially affecting all UNOS regions. Finally, the delta variant of SARS-CoV-2 created a wave of COVID-19 between July 2021

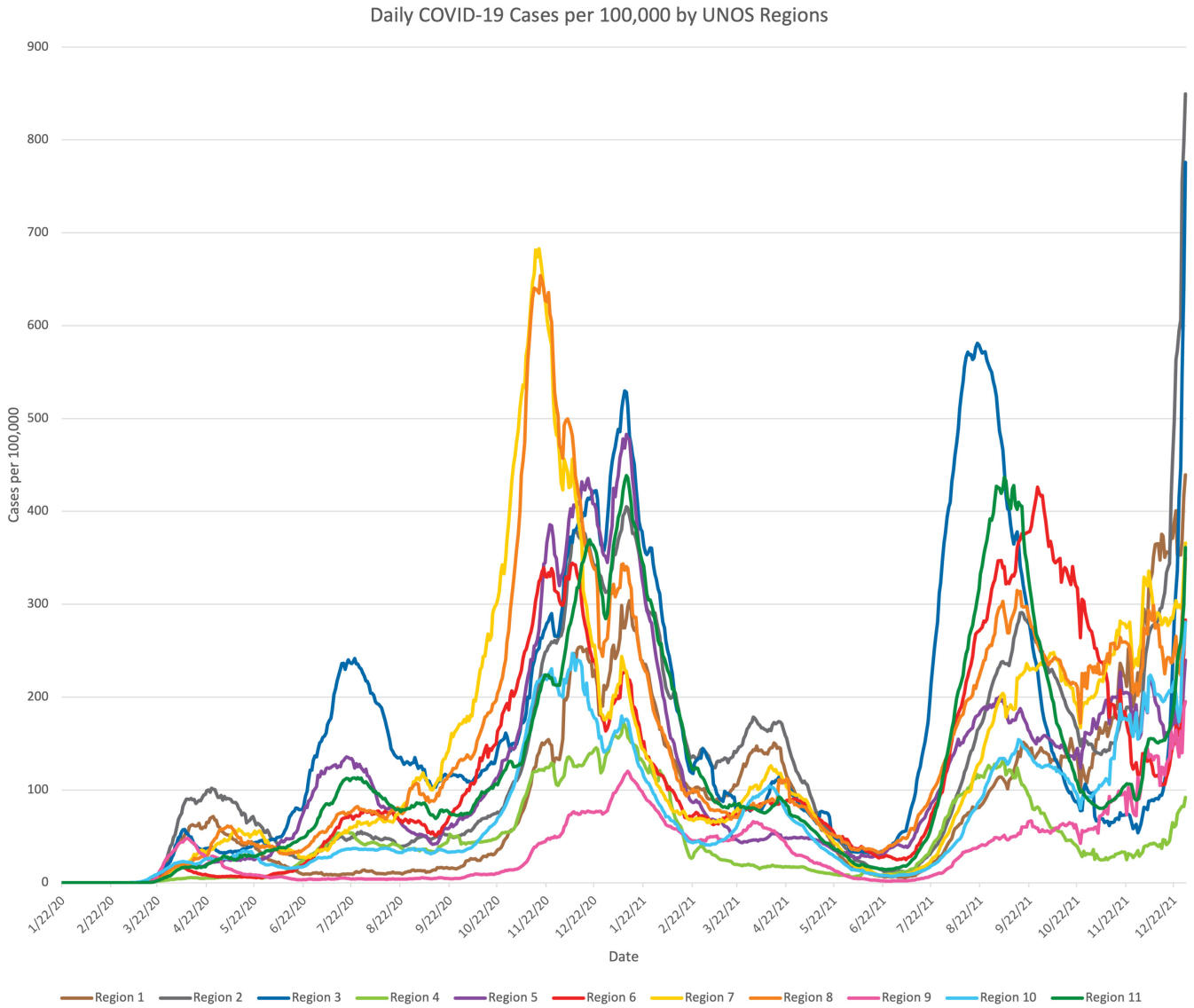

FIGURE 1 COVID-19 cases per 100,000 population across UNOS regions over the period January 2020 to December 2021 (data obtained from CDC)

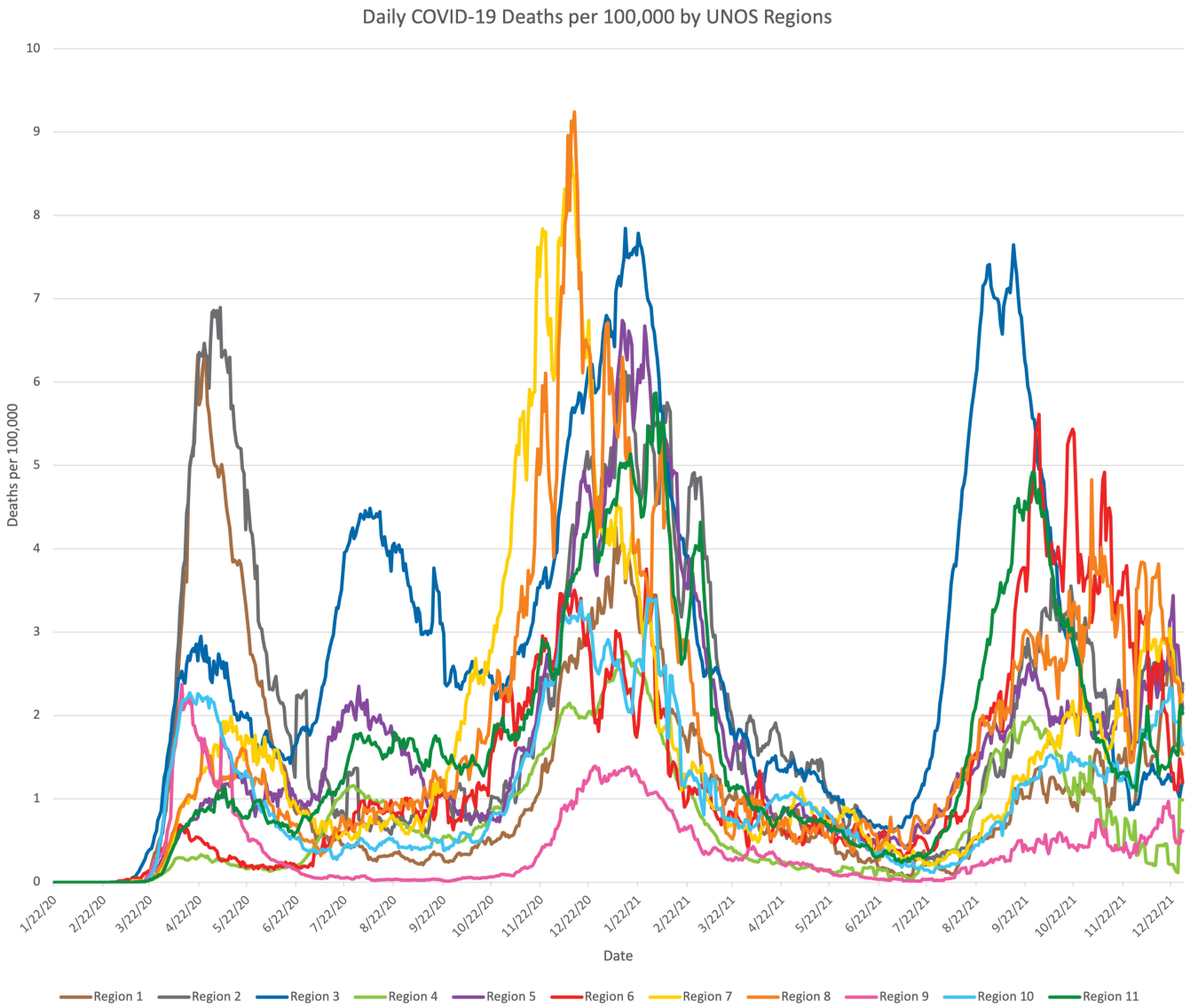

FIGURE 2 COVID-19 deaths per 100,000 population across UNOS regions over the period January 2020 to December 2021 (data obtained from CDC)

and November 2021 and had a pronounced impact on regions 3, 5, 7, 8, and 11. The case numbers and mortality during the delta wave in some of these regions (Midwest and Southeast US such as regions 3, 8, and 11) were similar or even higher to those experienced by the first wave of COVID-19 centered around the Northeastern United States.

UNOS reported that 2021 was a historic year in organ transplantation with more than 41,000 transplants performed across the nation.[6] This is a commendable effort of the transplant community in continuing to provide essential care to patients with end-stage organ disease. However, each region has faced different challenges at different times. Transplant rates and outcomes have been significantly impacted by the pandemic based on community characteristics and vaccination rates.[7-9] Studies have demonstrated that patients from communities of color, lower socioeconomic status, poorer access to healthcare and rural location have significantly worse outcomes from COVID-19 infections.[10] These high-risk communities are not equally distributed across the United States. Transplant centers that serve a higher proportion of rural and underserved communities or are in geographies with low vaccination rates are likely to have disproportionately worse survival outcomes.

In summary, the SRTR has potentially introduced bias into risk-adjusted performance outcomes reporting that unintentionally favors certain geographies and populations. We believe the decision by the SRTR to only censor the period corresponding to the first COVID-19 wave creates a disparity for centers in regions outside the Northeast as they were less impacted by this wave. The SRTR committee decided that reporting of metrics would return to normal, and the period of data censoring would be a "black hole period" as the calculation of organ-specific metrics would not be uniform. They did note that the intent of data censoring was only for the risk-adjusted models. However, risk-adjusted models are likely to affect transplant centers differently due to different waves and timing of the pandemic. Although early transplant center behavior patterns

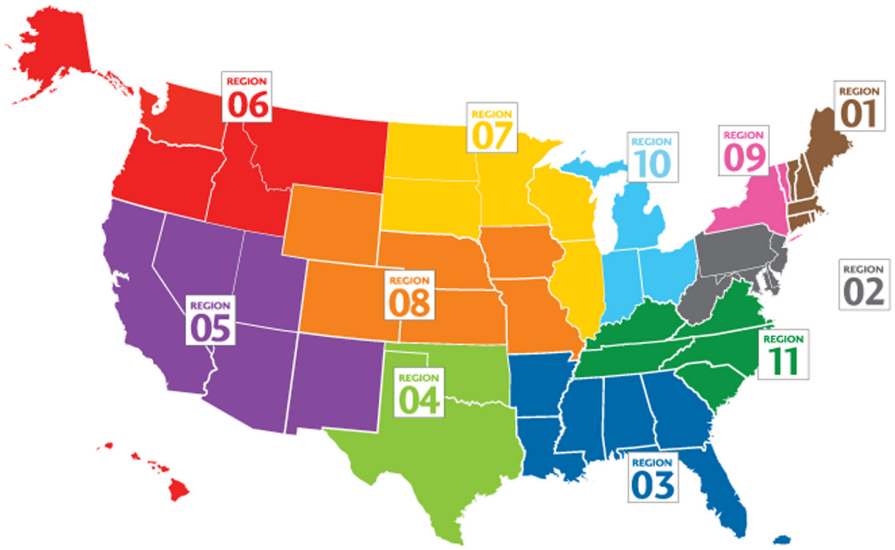

FIGURE 3 UNOS regions map

were acutely affected by the first wave, transplant rates and transplant mortality are likely to have affected centers differently. The pandemic peak from October 2020 to March 2021 affected nearly every UNOS region in the United States (Figure 2) and had the highest mortality rates. Furthermore, the delta wave strongly impacted the Southeast, Midwest, and Northwest (regions 3, 6, 8, 11), and less significantly impacted the Northeast. Additionally, the effects of the Delta and even the current Omicron variants have not been taken into consideration. Hence, we disagree with the SRTR's stance that the risks of bias were minimal, as we are unsure of how the different metrics were impacted by COVID-19 waves.[4] We believe that a critical review of these effects is essential prior to any data reporting or censoring that could affect all transplant centers differently.

We are proposing two potential solutions to address data censoring inequity:

1. Censoring all data during significant COVID-19 waves from the beginning of the pandemic irrespective of location or timing.
2. Collecting the data but halt all public reporting of data until the full impact of the pandemic is understood. Once sufficient data are analyzed and accounted for, prior to data reporting, it would be essential to include COVID-19 infection into the risk calculation, particularly with respect to deaths or outcomes directly or indirectly attributed to COVID-19.

The SRTR is not required to seek public comment on changes in data reporting or censoring. Due to the extraordinary circumstances of the pandemic, we also believe that an opportunity for public comment is necessary to allow for all perspectives to be represented in a critical decision that impacts every transplant program differently.

We acknowledge that the data discussed in this paper are acquired from public databases with intrinsic bias and do not necessarily reflect the exact circumstance of transplant patients. Nevertheless, extrapolating population-based data to transplant patients is justifiable since these dynamics significantly impact transplant centers in numerous ways.[11]

Medical professionals including transplant teams have been under immense stress to continue to perform at high level and provide care for severely ill patients. It is critical to the transplant community that the SRTR maintains integrity in data and equity in reporting. Transplant programs should not suffer lower performance measurements secondary to potentially biased and inequitable censoring of data.

DISCLOSURE

The authors of thismanuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in CDC, SRTR, OPTN, WHO databases - References 1, 2, 4, 6 in the manuscript.

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REFERENCES

1. WHO. WHO Coronavirus (COVID-19) Dashboard. Accessed January 28, 2022; 2022. https://covid19.who.int
2. CDC. COVID Data Tracker. Accessed January 28, 2022; 2022. https://covid.cdc.gov/covid-data-tracker/#datatracker-home
3. Nicola M, Alsafi Z, Sohrabi C, et al. The socio-economic implications of the coronavirus pandemic (COVID-19): a review. *Int J Surg*. 2020;78:185-193. 10.1016/j.ijsu.2020.04.018
4. SRTR. COVID-19 Related Changes. Accessed January 28, 2022; 2022. https://www.srtr.org/faqs/covid-19-related-changes/
5. Ong SWX, Chiew CJ, Ang LW, et al. Clinical and virological features of severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) variants of concern: a retrospective cohort study comparing B.1.1.7

(Alpha), B.1.351 (Beta), and B.1.617.2 (Delta). *Clin Infect Dis*. 2021. 10.1093/cid/ciab721
6. OPTN. OPTN Data Reports. Accessed January 28, 2022; 2022. https://optn.transplant.hrsa.gov/data/view-data-reports/
7. Boyarsky BJ, Po-Yu Chiang T, Werbel WA, et al. Early impact of COVID-19 on transplant center practices and policies in the United States. *Am J Transplant*. 2020;20(7):1809-1818. 10.1111/ajt.15915
8. Goff RR, Wilk AR, Toll AE, McBride MA, Klassen DK. Navigating the COVID-19 pandemic: Initial impacts and responses of the Organ Procurement and Transplantation Network in the United States. *Am J Transplant*. 2021;21(6):2100-2112. 10.1111/ajt.16411
9. Kumar D, Manuel O, Natori Y, et al. COVID-19: a global transplant perspective on successfully navigating a pandemic. *Am J Transplant*. 2020;20(7):1773-1779. 10.1111/ajt.15876
10. Perry BL, Aronson B, Pescosolido BA. Pandemic precarity: COVID-19 is exposing and exacerbating inequalities in the American heartland. *Proc Natl Acad Sci*. 2021;118(8):e2020685118. 10.1073/pnas.2020685118
11. Mohan S, King KL, Husain SA, Schold JD. COVID-19-associated mortality among kidney transplant recipients and candidates in the United States. *Clin J Am Soc Nephrol*. 2021;16(11):1695-1703. 10.2215/CJN.02690221

How to cite this article: Subramanian V, Anderson C, Karp S, et al. COVID-19 and transplantation—Data censoring. *Am J Transplant*. 2022;00:1–5. doi:10.1111/ajt.17065