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Data carve out in the midst of the COVID-19 pandemic

To the Editor:

In the viewpoint of Subramanian et al.,[1] the authors suggest that the Scientific Registry of Transplant Recipients (SRTR) decision to implement a data "carve out" from March 13, 2020 to June 12, 2020, due to the COVID-19 pandemic, could potentially result in systematic geographic bias, particularly as viral prevalence has varied geographically. While the authors indicate that this particular statistical approach is "unfair," it is unclear which particular metric they are referring to, thus making their claims of "potential" biases difficult to assess.

As members of the SRTR Review Committee (SRC), we disagree with the authors' interpretation of the "carve out" and the suggested solutions they provide. We have extensively reviewed incoming data throughout the pandemic and have advised the SRTR to take steps to avoid inequity against specific sites or regions.

First, the carve out period was selected due to the national disruption in transplant operations, not because of the high rate of infections and mortality (largely concentrated in urban centers, as noted by the authors). We believed that the near-total disruption of normal operations at transplant centers and organ procurement organizations, even outside regions of high prevalence, supported" carving out" data during a period when there was an incomplete understanding of the level of risk or the appropriate management of our patients.[2] Over the ensuing months, we observed a return of transplant operations, which eventually surpassed previous activity, regardless of region.

Secondly, the carve out, as implemented, excludes follow-up for any patient transplanted prior to March 13, 2020, on March 12, 2020. In effect, this acknowledges that patients transplanted prior to the onset of the pandemic would not be evaluated beyond this point. In addition, patients transplanted during the first few weeks of the pandemic are not included in subsequent evaluations. Patients transplanted after the carve out, once transplant operations mostly resumed to pre-pandemic levels, are followed per normal methods. While we acknowledge potential variation at the center level, our choices are reflective of the observed effect of the pandemic systemwide.

Finally, the authors provide two potential solutions which are not implementable. Eliminating data reporting completely during a pandemic of over 2 years duration runs counter to the SRTR mission "to provide timely and accurate information on the performance of Organ Procurement Organizations (OPOs) and transplant programs."[3] While we agree that there were additional waves, these occurred in the setting of better understanding of non-pharmaceutical interventions, widespread vaccination, and a therapeutic armamentarium that mitigated the associated rates of graft failure and death in our patient populations.[4] Additionally, it is unclear how we would define "significant" COVID-19 waves in order to implement the authors' suggestion to censor data during such waves, particularly if the waves vary regionally and do not appear to have adversely impacted outcomes on a regional level. The SRC noted that, given the 2.5-year cohorts included in the evaluations, waves have now affected all areas of the country. To this end, in January 2021, changes to the SRTR website address the impact of the pandemic on transplant operations throughout the US. Lastly, as noted by the authors, social determinants of health vary widely across centers within a particular geographic region and the impact of "significant" COVID-19 waves is not uniform across centers even within a small geographic area.

As noted by Subramanian et al.,[1] it is critical that the SRTR continue its important functions. We believe, as a multidisciplinary review committee, that this remains our focus. We will continue to monitor the data carefully and closely, with the goal of supporting transplant activities for the benefit of our patients.

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