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Navigating the COVID-19 pandemic: Initial impacts and responses of the Organ Procurement and Transplantation Network in the United States

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COVID-19 has been sweeping the globe, hitting the United States particularly hard with a state of emergency declared on March 13, 2020. Transplant hospitals have taken various precautions to protect patients from potential exposure. OPTN donor, candidate, and transplant data were analyzed from January 5, 2020 to September 5, 2020. The number of new waiting list registrations decreased, with the Northeast seeing over a 50% decrease from the week of 3/8 versus the week of 4/5. The national transplant system saw near cessation of living donor transplantation (−90%) from the week of 3/8 to the week of 4/5. Similarly, deceased donor kidney transplant volume dropped from 367 to 202 (−45%), and other organs saw similar decreases: lung (−70%), heart (−43%), and liver (−37%). Deceased donors recovered dropped from 260 to 163 (−45%) from 3/8 compared to 4/5, including a 67% decrease for lungs recovered. The magnitude of this decrease varied by geographic area, with the largest percent change (−67%) in the Northeast. Despite the pandemic, discard rates across organ has remained stable. Although the COVID-19 pandemic continues to evolve, OPTN data show recent evidence of stabilization, an indication that an early recovery of the number of living and deceased donors and transplants has ensued.

KEYWORDS
donors and donation: deceased, donors and donation: living, ethics and public policy, infection and infectious agents - viral, infectious disease, organ procurement, organ procurement and allocation, Organ Procurement and Transplantation Network (OPTN), organ transplantation in general

1 | INTRODUCTION

On January 30, 2020, the World Health Organization declared a Public Health Emergency of International Concern related to the newly discovered coronavirus disease 2019 (COVID-19).[1] The United States (US) subsequently declared a public health emergency related to COVID-19 on January 31, 2020, and a national state of emergency on March 13, 2020.[2] Despite the adoption of

Abbreviations: CDC, Centers for Disease Control; COD, causes of death; COVID-19, coronavirus disease 2019; CPRA, Calculated Panel Reactive Antibodies; DSA, donation service area; HHS, Department of Health and Human Services; HRSA, Health Resources and Services Administration; LAS, lung allocation score; MELD, model for end-stage liver disease; MERS, Middle East respiratory syndrome coronavirus; NM, nautical mile; OPO, Organ Procurement Organization; OPTN, Organ Procurement and Transplantation Network; PELD, pediatric end-stage liver disease; SARS, severe acute respiratory syndrome; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SRTR, Scientific Registry of Transplant Recipients; UNOS, United Network for Organ Sharing; US, United States.

[Correction added on 15 May, 2021, after first online publication: "May 1, 2020 to May 9, 2020" has been corrected to "January 5, 2020 to September 5, 2020" in the sentence from Abstract: "OPTN donor, candidate, and transplant data were analyzed from January 5, 2020 to September 5, 2020. "]

public health measures such as social distancing and closure of non-essential businesses, the rates of COVID-19 in the US continued at a pace above other countries.[3] Centers for Disease Control (CDC) data showed that the US (and territories) currently lead the world in the number of confirmed cases at over 6.6 million from January 21 to September 17, 2020,[4] with three states reporting over 600,000 cases and five reporting over 200,000. The long-term impacts of COVID-19 on the healthcare system, and more specifically on the transplant system in the United States, remain unknown, but the initial impact on solid organ transplantation was dramatic.

The risks of disease transmission through solid organ transplantation and the implications for transplant recipients, transplant center staff, and Organ Procurement Organization (OPO) staff are unknown.[5] Recent publications detail potential impacts to donor organs, including kidney, liver, and heart, though sample sizes are small, data are limited, and not all reports have undergone peer review.[6-11] Given the respiratory nature of COVID-19, there are obvious impacts to the lungs. As suggested by Michaels et al., the initial responses were guided by the experience from past infectious disease emergencies, such as severe acute respiratory syndrome coronavirus (SARS), Middle East respiratory syndrome coronavirus (MERS), West Nile virus, and Zika. This included appropriate donor, patient, and staff screening, recipient evaluation, and development of patient logistics plans, such as multi-listing, to navigate the effects of the COVID-19 pandemic on transplantation. Moris et al. noted the importance of customizing clinical decision-making by patient within hospitals, including consideration of resource availability (such as staff and testing) during COVID-19 balanced with medical urgency (which may vary by organ) and transparent patient discussions regarding potential risk of transmission or death given the limited knowledge of COVID-19 implications.[5,12] An article detailing the Italian experience regarding COVID-19 and transplant described the preventative measures, including infection control and hygiene, limiting surgical activities, and screening/isolation that were implemented in an attempt to ensure safe practice.[13] Kumar et al. discussed various mitigation strategies and considerations, such as embedding transplant infectious disease specialists in programs.[14] Transplant clinicians voiced concerns and urgency for patients with debilitating, life-threatening illnesses, noting that lack of access to transplantation could result in high mortality.[15] Wall et al. presented a discussion on ethical decision-making for organ transplantation in a time of resource scarcity and practical limitations,[16] while Fix et al. and Tzedakis et al. proposed a template of clinical recommendations for liver transplantation.[17,18] Early documentation of the effect of COVID-19 on future need for organ transplantation, Chen et al. reported a successful lung transplantation in a patient with end-state respiratory failure due to COVID-19 infection.[19]

Qualitative data continue to be shared worldwide regarding the impact to transplantation from COVID-19[20]; reports described decreased transplant volumes, complete suspension of live donation in some centers, approaches to donor testing, and modified recipient follow-up through tools such as telehealth.[21,22] Studies from France and Spain showed profound decreases in deceased donor transplantation.[23,24] In the United States, Boyarsky et al. and Cholankeril et al. showed a major decrease in waiting list registrations and an increase in waitlist mortality, specifically for kidney transplantation.[25,26]

In March 2020, the Centers for Medicare and Medicaid issued guidance recommending that transplantation surgeries, classified as Tier 3b procedures, should not be postponed, if possible.[27] This allowed the transplant community to make decisions on a candidate-by-candidate basis to reduce the risk to transplant candidates, living donors, recipients, and care providers while continuing, when possible, to provide essential transplant services.

This report describes the initial impacts of the pandemic on the transplant system, including deceased and living donation as well as transplant candidates and recipients, in the United States and the responses of the OPTN to mitigate adverse outcomes.

2 | DATA AND METHODS

This study used data from the OPTN. The OPTN data system includes data on all donors, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the OPTN, and has been described elsewhere. The Health Resources and Services Administration, HHS, provides oversight to the activities of the OPTN contractor. All OPTN data analyzed are as of September 18, 2020, and are subject to change based on future data submission and correction. This is a retrospective analysis of all waiting list candidates, transplant recipients, and deceased donors from January 5, 2020 to September 5, 2020; for registrations and transplants, analysis was limited to kidney, liver, heart, and lung.

For all metrics, weekly trends (defined as Sunday–Saturday) are reported to determine the ongoing impact of the COVID-19 pandemic on transplantation. Deceased and living donor transplants and new waiting list registration counts are reported by organ, and geographic area (defined in Table 1, includes US census population data[28]). Counts of deceased donors recovered are reported by geographic area. Deceased donor organs recovered are reported by organ. Changes in causes of death (COD) resulting in organ donation were examined by week. The discard rate, defined as the percentage of organs not transplanted out of all organs recovered for the purpose of transplantation, is summarized by organ and COVID-19 era utilizing March 13, the date a national state of emergency was declared, as the beginning of the COVID-19 era. The percentage of deceased donor transplants recovered and transplanted within the same donation service area (DSA) and nautical mile (NM) distance between the transplant center and donor hospital are summarized with medians by COVID-19 era utilizing March 13, 2020 as the beginning of the COVID-19 era. The distribution of medical urgency for liver, heart, and lung recipients was examined by week. For kidney recipients, the proportion of high (98–100%) Calculated Panel Reactive Antibodies (CPRA) transplants was reported.

The OPTN has collected reasons for individual candidate inactivation on the waiting list since 2006. On March 18, 2020, the OPTN

TABLE 1 Definitions of geographic areas examined

Geographic Area	States Included	Population[a]
Great Lakes	Illinois, Indiana, Michigan, Ohio, Wisconsin	46,931,883
Mid-Atlantic	Delaware, Maryland, Pennsylvania, Virginia, Washington DC, West Virginia	30,842,921
North Midwest	Colorado, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota, Wyoming	27,650,167
Northeast	Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont	43,304,019
Northwest	Alaska, Hawaii, Idaho, Montana, Oregon, Washington	16,700,746
South Midwest	Oklahoma, Texas	32,644,924
Southeast	Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee	77,268,316
Southwest	Arizona, California, Nevada, New Mexico, Utah	55,019,616

[a]2018 U.S. census data. Available from https://data.census.gov/cedsci/.

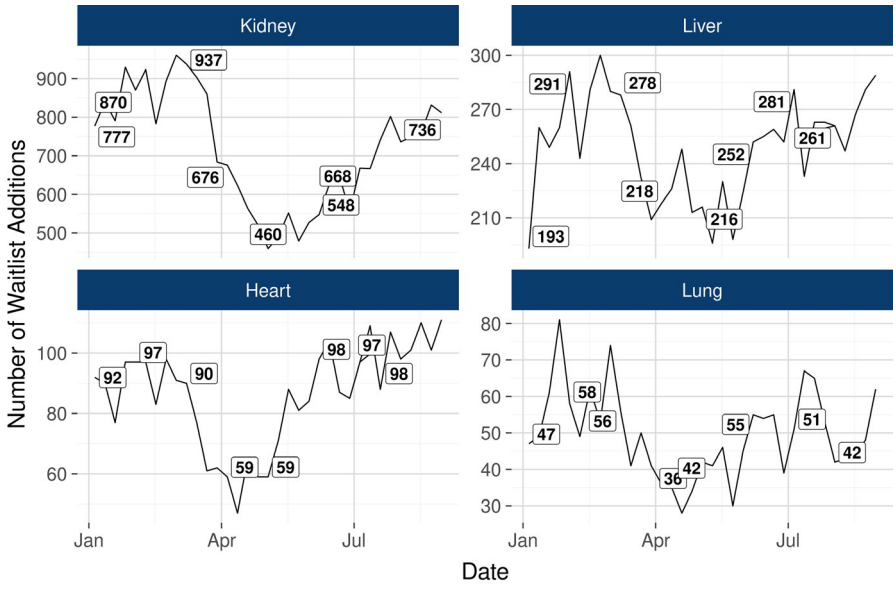

FIGURE 1 New waiting list registrations by week and organ from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

added a new reason for inactivation on the waiting list system to identify patients inactivated in relation to COVID-19. This code allows transplant hospitals to indicate that individual patients are temporarily unavailable (or inactive) for organ offers and specifies the reason of COVID-19 precaution. The volume of new inactivations due to COVID-19 is reported by week. Registrations may be counted multiple times if the same registration is inactivated, reactivated, and then again inactivated in different weeks.

All analyses were performed using R version 3.5.0.[29] Formal statistical comparisons were not made.

3 | RESULTS

The number of new waiting list registration for kidney, liver, heart, and lung began decreasing significantly in early March. There were approximately 900 new kidney waitlist registrations per week prior to the pandemic (Figure 1). This decreased by approximately 50% to 460 in early May. Similar changes were seen in registrations for other organs. All geographic areas saw a decrease in the number of new waiting list registrations beginning in March or early April (Figure 2). The Northeast saw over a 50% decrease between the weeks of 3/8 (N = 195) and 4/5 (N = 91). Waitlist registrations began to increase in May; however, recovery was not complete and in September new registrations per week remained approximately 10% below pre-pandemic levels.[30]

Waitlist inactivations due to "COVID-19 precaution," a newly available data coding option from the OPTN, increased rapidly in March (Figure 3). This visibly tapered by mid- to late May and remained low from May to September.

The number of deceased donors recovered for transplant began decreasing in March (Figure 4). The COD for donors

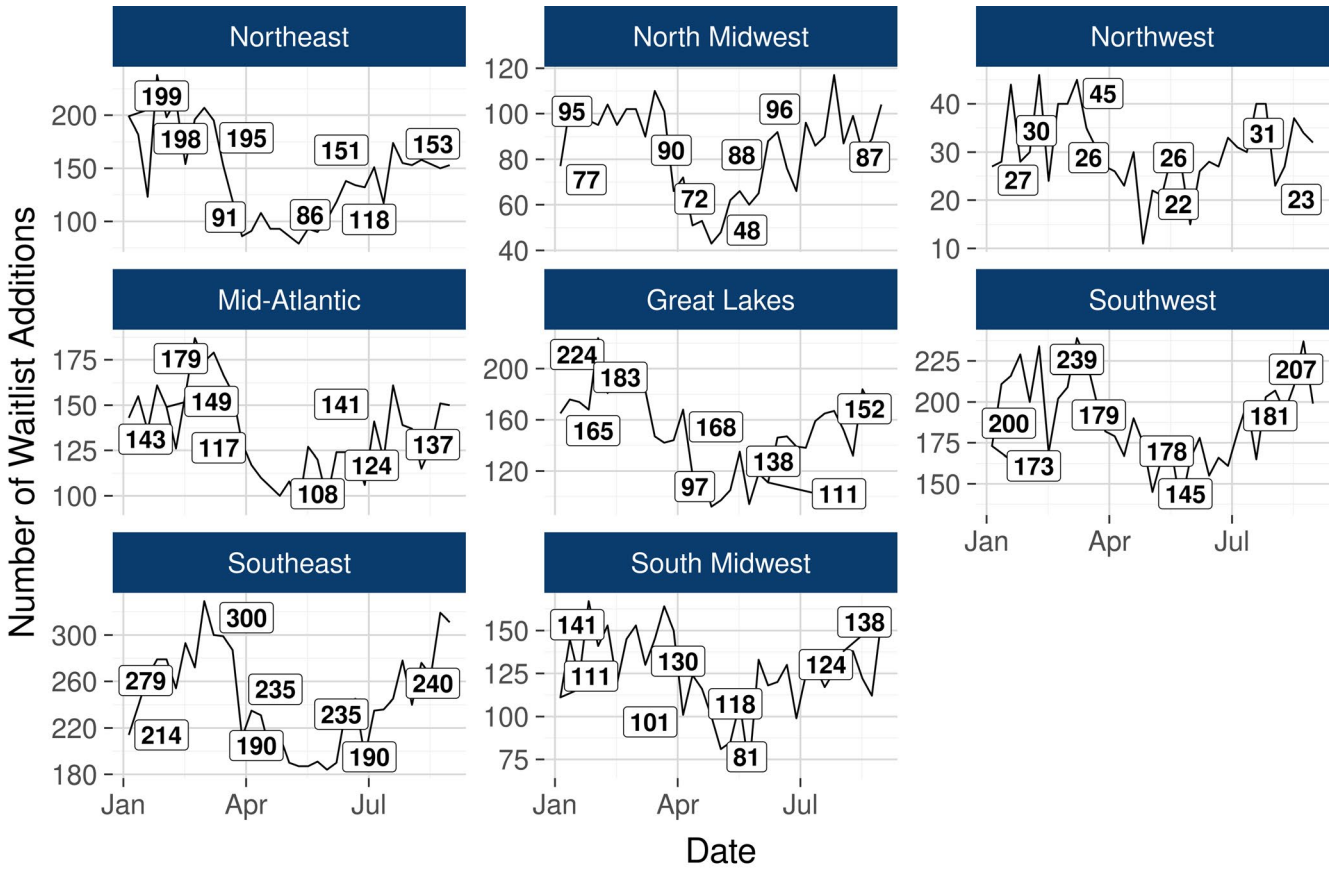

FIGURE 2 New waiting list registrations by week and geographic area from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

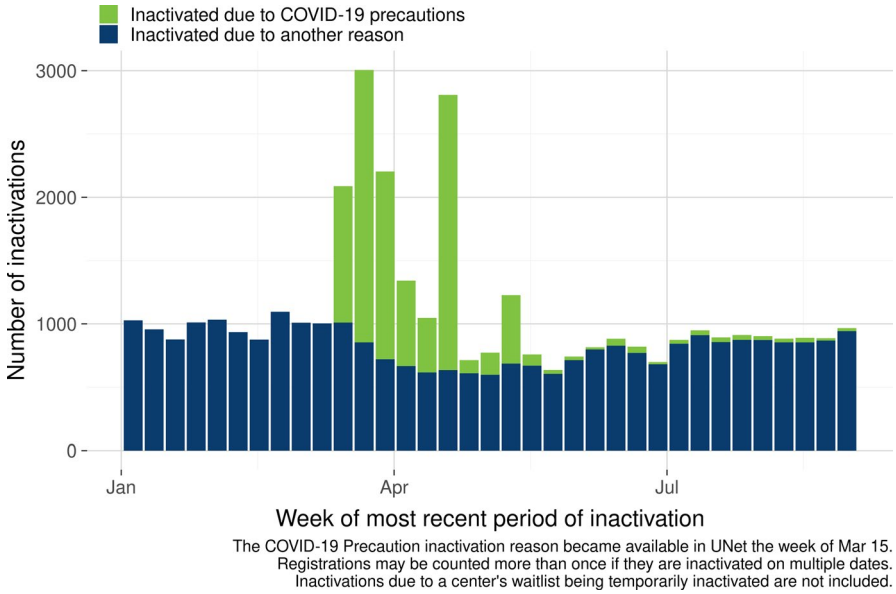

FIGURE 3 Volume of Inactivations by COVID-19 precautions or another reason from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

remained unchanged for anoxia and other (Figure 5), and weekly variation was visible for the percentage of deaths related to stroke and head trauma deaths. During the week of 8th March, there were 260 deceased donors recovered for transplant, and in the week of April 5th the number dropped to 163. Lungs recovered for transplant were down 67% from the week of March 8th (N = 120) compared to the week of April 5th (N = 39) (Figure 6). All geographic areas saw a decrease in the number of donors

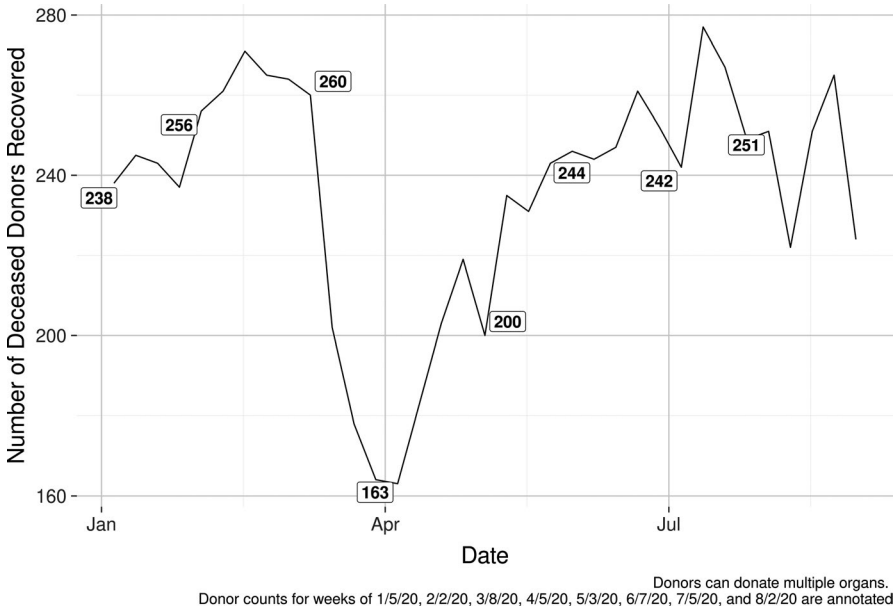

FIGURE 4 Volume of deceased donor recovered nationally by week from 1/5/20 to 9/5/20

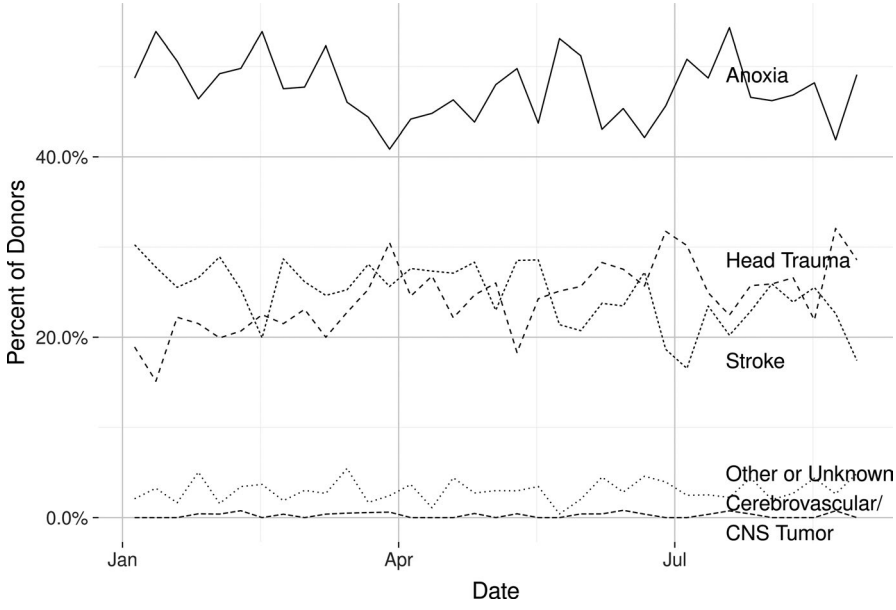

FIGURE 5 Cause of death for deceased donors by week from 1/5/20 to 9/5/20

recovered for transplant from March to April (Figure 7). The magnitude of this decrease again varied by geographic area. The percent decrease from the week of March 8th and the week of April 5th was the largest in the Northeast, where the volume of donors decreased from 24 to eight (67%). Subsequently, there was an indication of some rebound to pre-COVID-19 weeks in certain geographic areas.

Kidney, liver, heart, and lung deceased donor transplant volumes began obvious declines in March (Figure 8). The volume of kidney transplants dropped from 368 the week of March 8th to 202 the week of April 5th (45% difference). Similar decreases of various magnitudes were seen in lung (70%), heart (43%), and liver (37%) transplants. Beginning mid-April, there was an appearance of a subsequent rebound and increase in the deceased donor transplant volume for kidney, liver, and heart, continuing through the most recent week analyzed. All geographic areas had lower transplant volumes in March (Figure 9) compared to prior months. There is evidence that the Northwest began to see a decline in transplant volume as early as February. The medical urgency for liver, heart, and lung transplant recipients is summarized in Figure 10. There was a noticeable drop in Heart Status 1 and 2 transplants in March and a subsequent rebound by May. For liver, there was a drop across all Status/MELD/PELD groups in March and still remains variable by week. Similarly, there was a consistent drop in

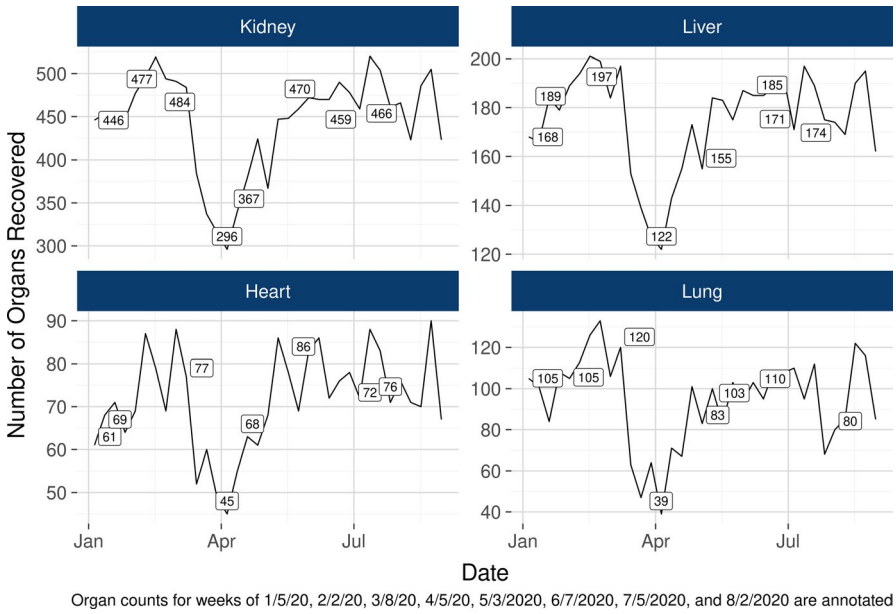

FIGURE 6 Volume of deceased donor organs recovered by organ and week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

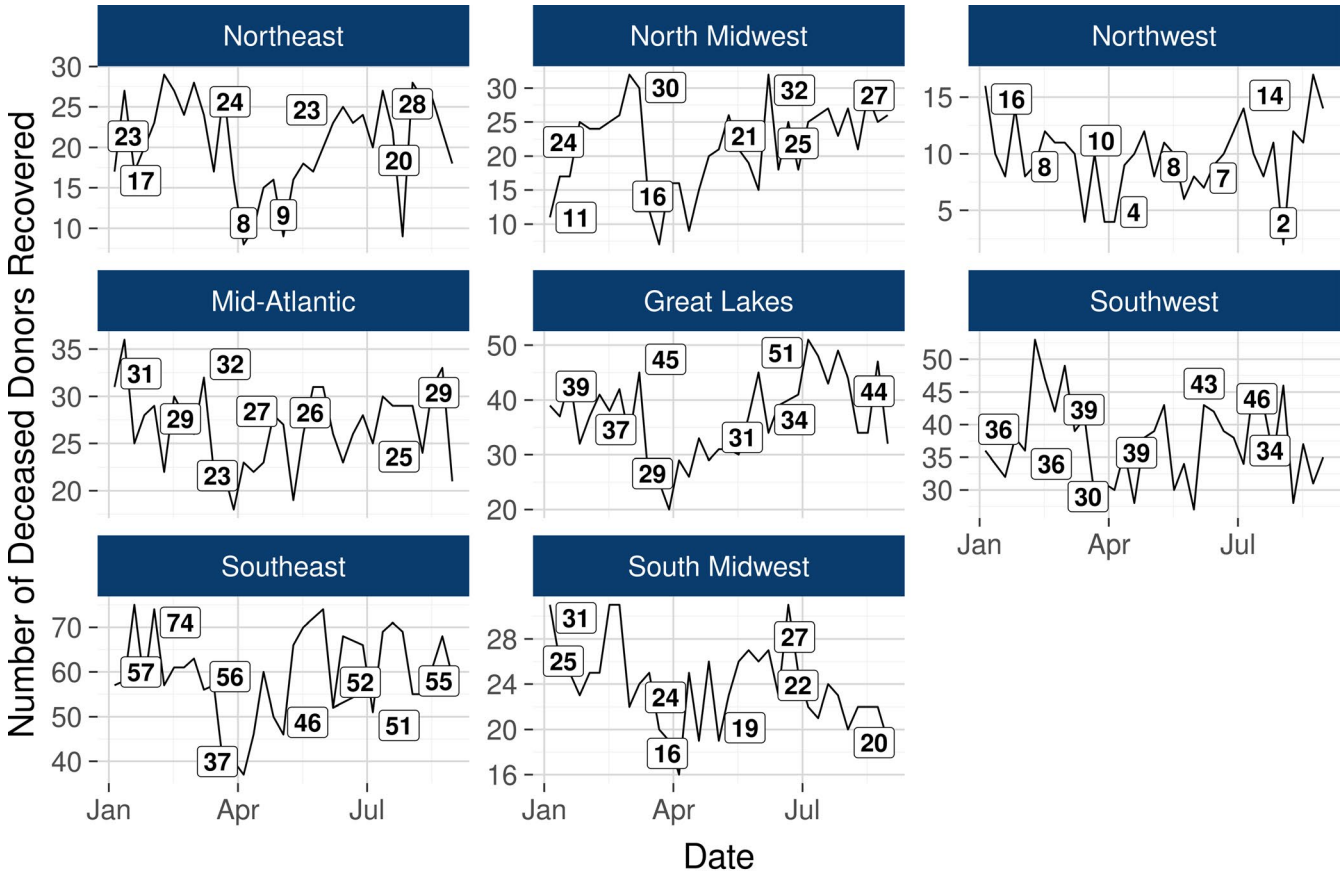

FIGURE 7 Number of deceased donors recovered by week and geographic area from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

all lung allocation score (LAS) groups with LAS 70+ remaining low after May. The volume of 98–100% CPRA (highly sensitized) kidney recipients displayed a sharp increase in March and subsequent rebound the next week (Figure 11). Kidney, liver, heart, and lung all saw minimal changes in the discard rate from the earlier to the later time period as shown in Table 2.

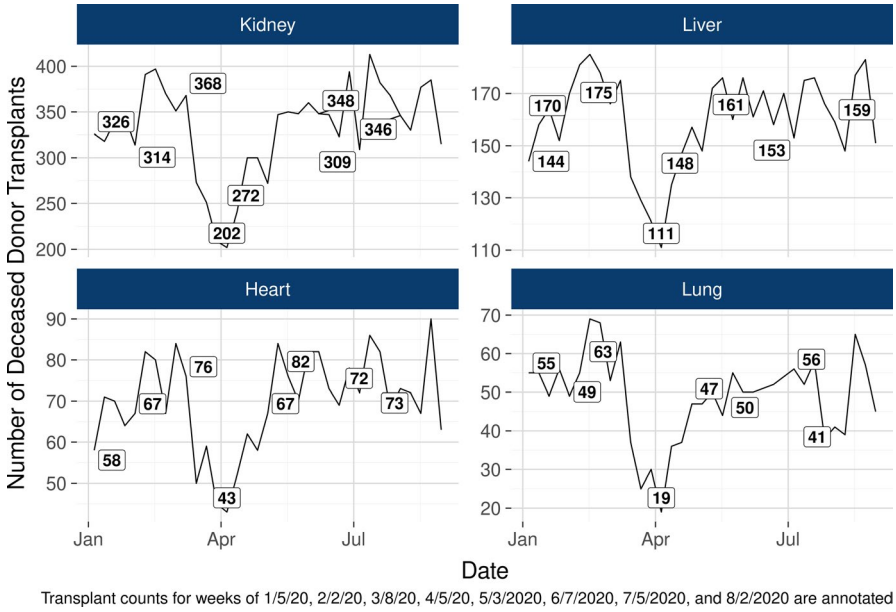

FIGURE 8 Number of deceased donor transplants by organ and week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

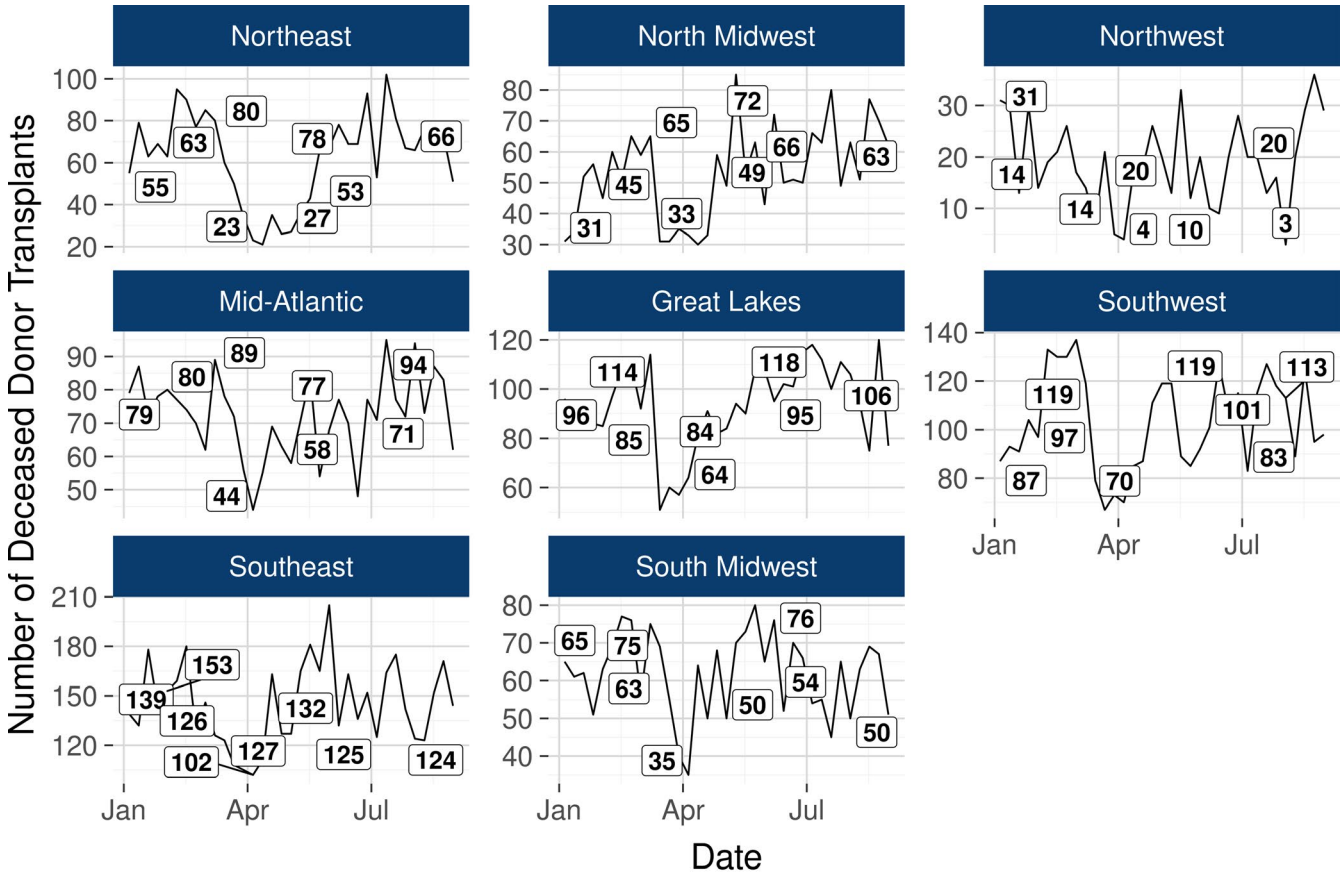

FIGURE 9 Deceased donor transplant volume by geographic area and week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

The median distance organs traveled increased slightly for livers pre- vs. post-COVID-19 (liver: 114 NM to 148 NM), but decreased slightly for all other organs (kidney: 70 NM to 67 NM, heart: 225 NM to 211 NM, lung: 179 NM to 176 NM) (Figure 12). It is important to note that liver allocation moved from DSA/OPTN regional geographic allocation units to concentric circles on February 4, 2020,

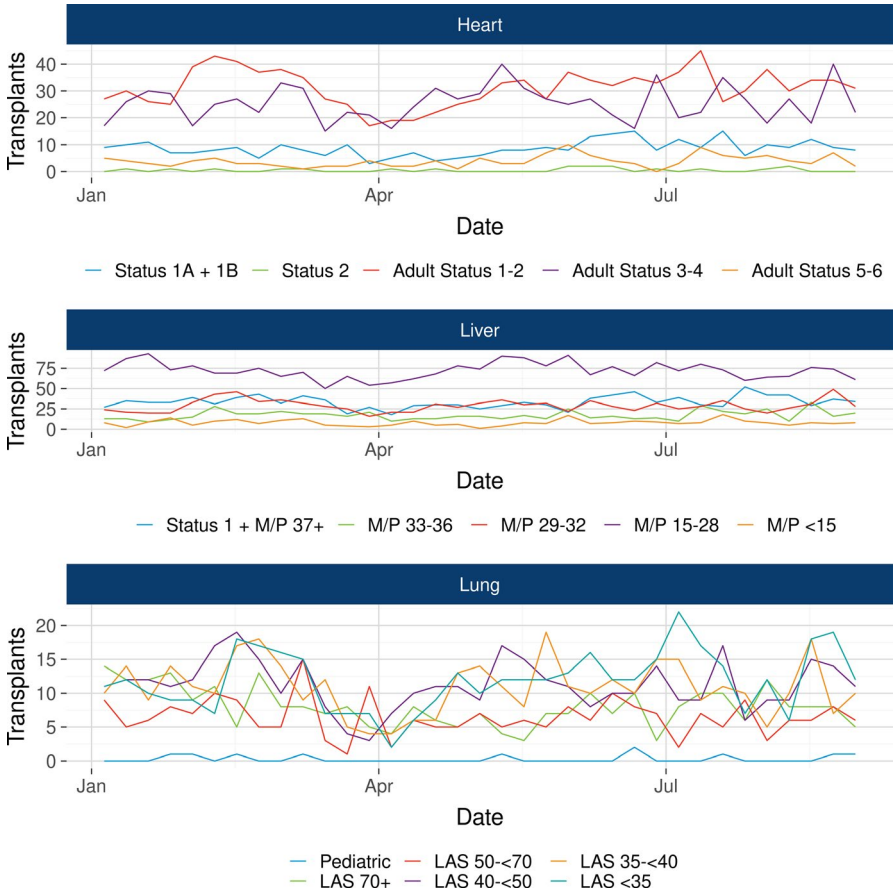

FIGURE 10 Heart, Liver, and Lung transplant recipient medical urgency status by week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

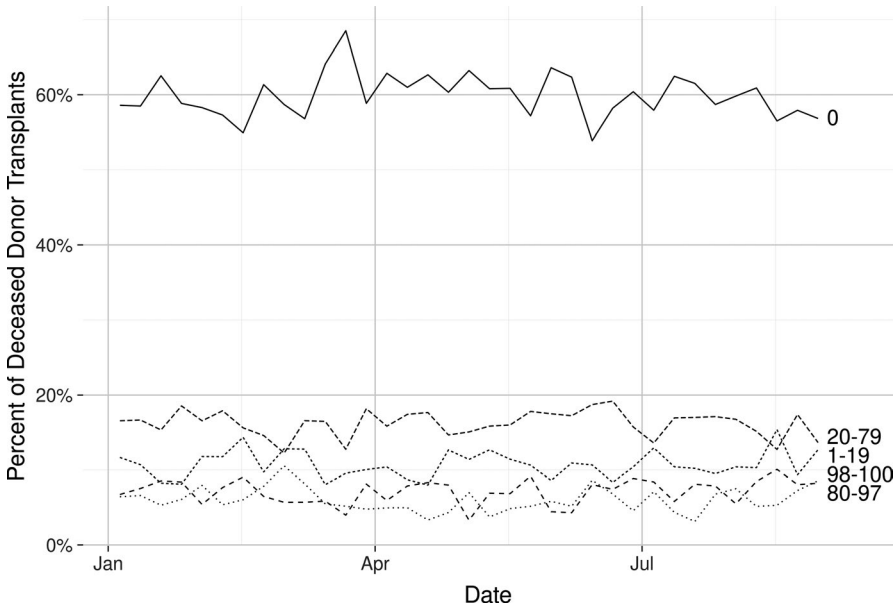

FIGURE 11 Kidney transplant recipient CPRA (%) group by week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

so the entire COVID-19 time period coincides with new allocation rules. Overall, the percent of transplants occurring within the same DSA of organ recovery decreased from 55% from 1/5/20-3/12/20 to 53% from 3/13/20-9/5/20. This change was predominantly driven by liver, which decreased from 49% local from 1/5/20-3/12/20 to 34% local from 3/13/20-9/5/20.

There was a substantial drop in living donor kidney transplants during COVID-19 and a lower number of living donor liver transplants. The volume of living donor kidney transplants dropped 92% from 138 the week of March 8th to just 11 in the week of April 5th (Figure 13). Living liver donor transplants also saw a drop of 62% from 13 the week of March 8th to five the week of April 5th. All geographic areas saw a drastic drop in the volume of living donor transplants being performed (Figure 14), with a few areas having zero living donor transplants in some weeks. Both show recent evidence of an increase in transplant across kidney and liver as well as all geographic areas. As of September 6th, overall deceased donor volume is up despite a national pandemic (8,397 in 2020 vs. 7,957 in 2019) but overall transplant volume remains lower, mostly driven by a decrease in living donation transplantation (26,097 in 2020 vs. 27,015 in 2019) and varies by organ.[30,31]

TABLE 2 Discard rate by organ and time period

	Organ Discard Rate by COVID Time Period	
Organ	1/5/20-3/12/20	3/13/20-9/5/20
Kidney	21.6%	20.7%
Liver	10.8%	9.1%
Heart	1.7%	0.7%
Lung	7.7%	4.3%

4 | DISCUSSION

The impact of the SARS-CoV-2 pandemic on the transplant healthcare system was abrupt, profound, and unprecedented. The initial OPTN response to the pandemic was based on an analysis of the major factors affecting patients and the operations of transplant centers and OPOs, putting into place emergency policy measures, data collection on COVID-19 donor testing and waitlist inactivations due to COVID-19, and processes with a goal of assuring safe organ donation and transplantation. These policies were designed to (1) reduce candidate, recipient, and living donor exposure to COVID-19, (2) avoid disadvantage for transplant candidates unable to safely access healthcare facilities for pre-transplant laboratory testing, (3) reduce transplant hospital administrative burden, and (4) provide OPOs and transplant hospitals efficient communication of COVID-19 testing status and results of donors, and transplant candidates. Transplant programs were, at their discretion, able to use a candidate's existing laboratory data to maintain medical urgent allocation priority, data submission requirements for recipient and living donor follow-up were relaxed, allowance for waiting time for non-dialysis

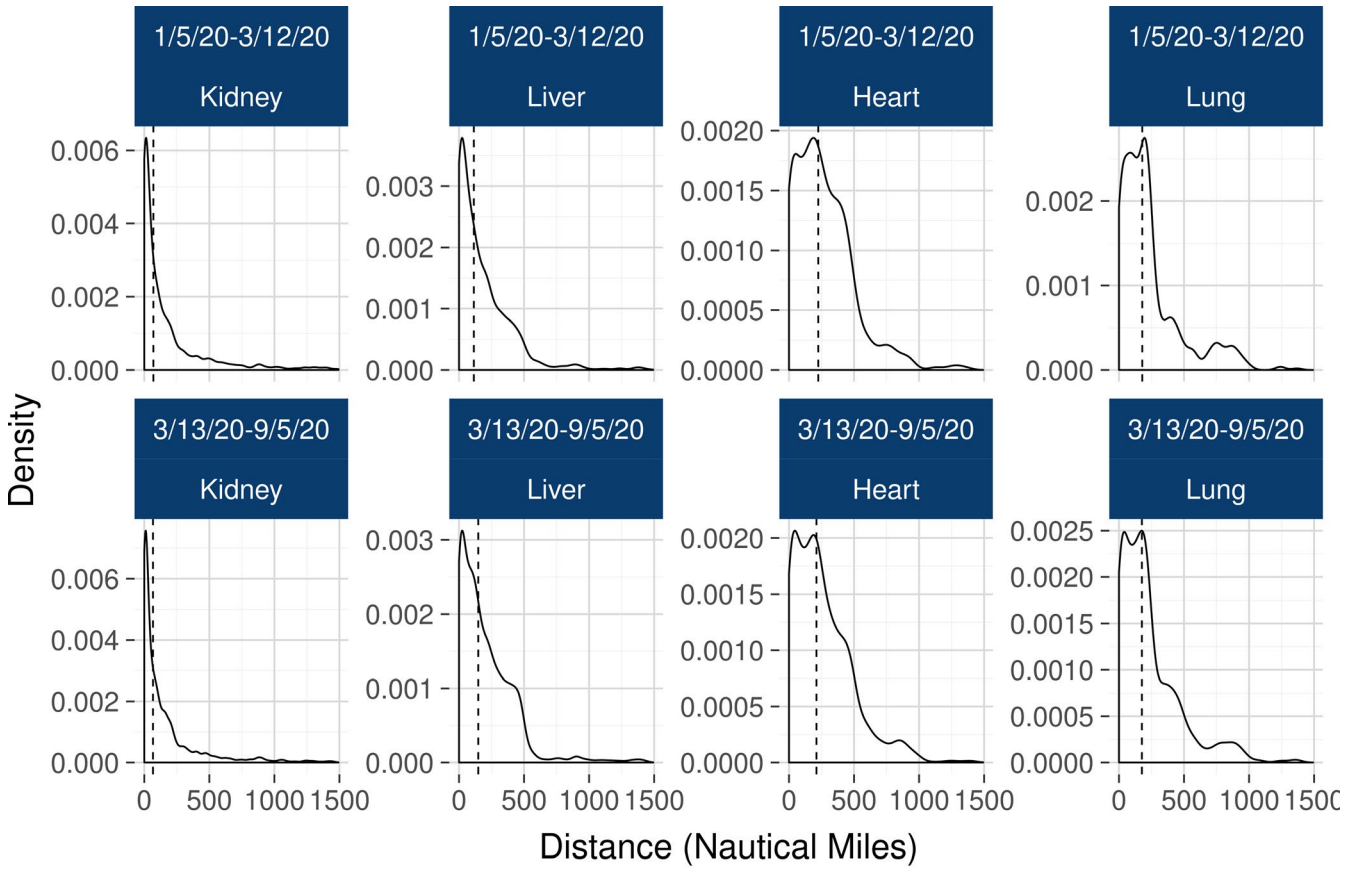

FIGURE 12 Distance between the donor hospital and transplant program by organ and time period [Color figure can be viewed at wileyonlinelibrary.com]

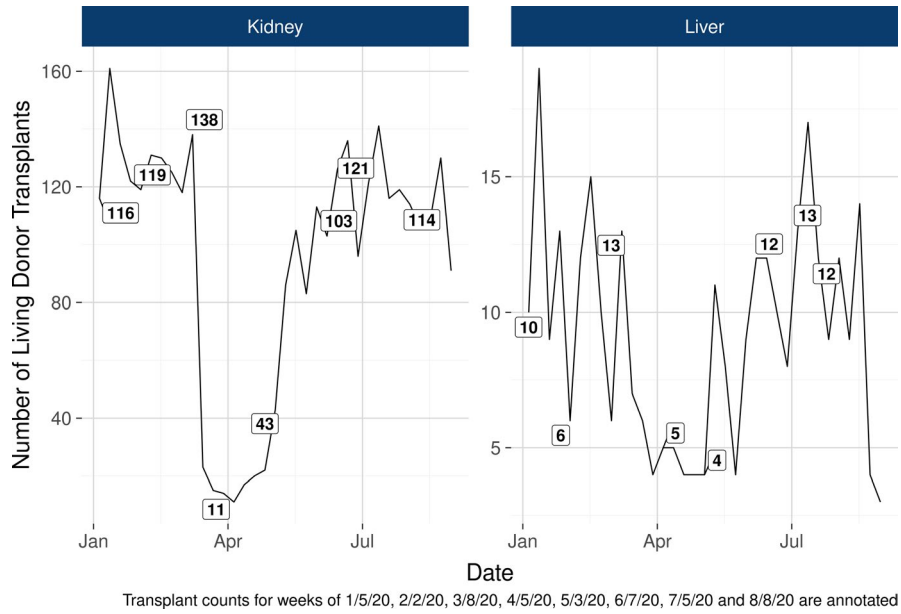

FIGURE 13 Number of living donor transplants by organ and week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

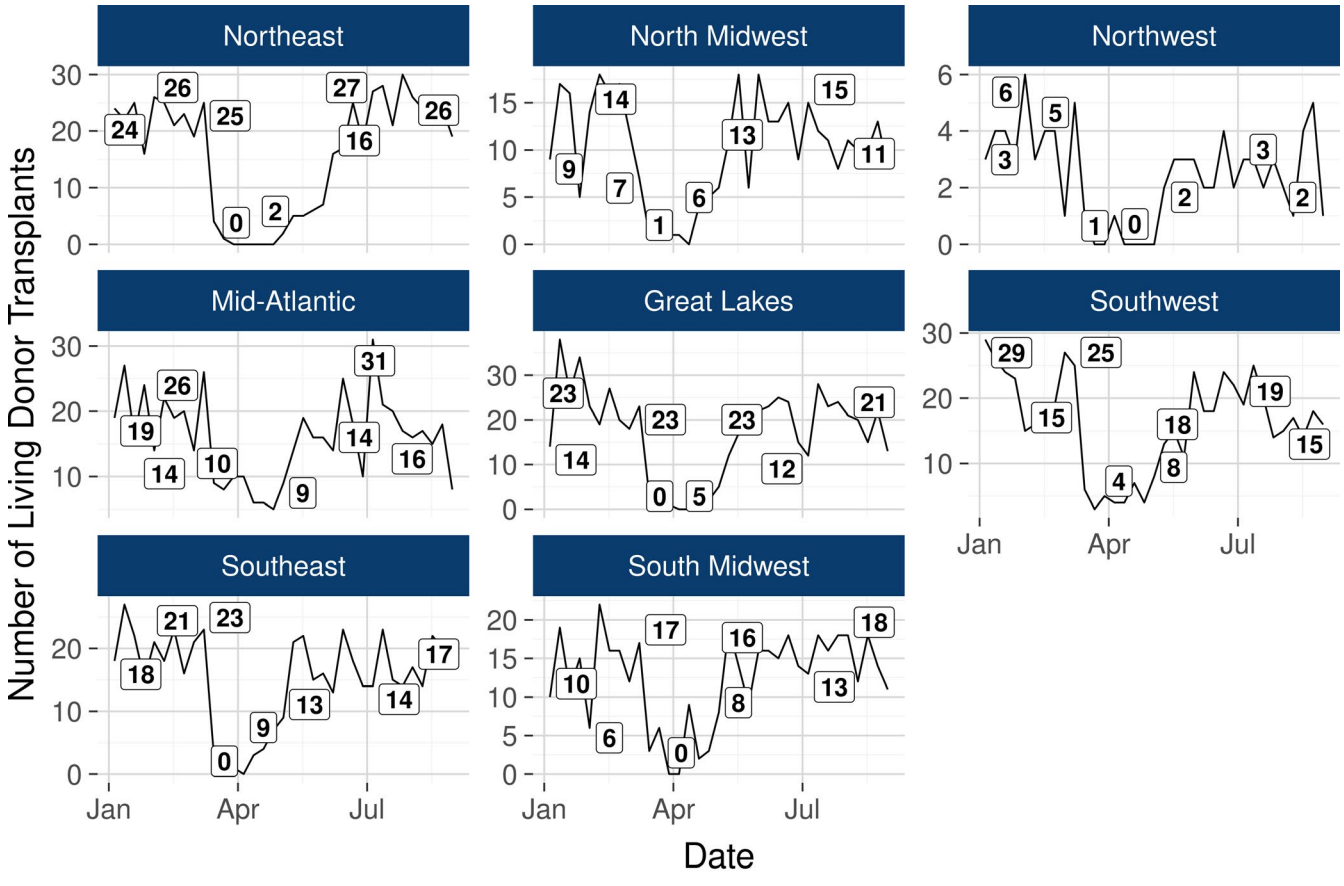

FIGURE 14 Number of living donor transplants by geographic area and week from 1/5/20 to 9/5/20 [Color figure can be viewed at wileyonlinelibrary.com]

kidney candidates to be backdated to the date the program intended to list the candidate was implemented, and data fields were added to allow reporting of COVID-19 testing, testing type, specimen type, and results as COVID-19 testing became available. Additionally, scheduled site surveys were postponed or conducted virtually at center or OPO discretion. The transplant community, government,

and the public were provided with access to real-time data on national and regional transplants, waitlist, and donor numbers. The OPTN Ad Hoc Disease Transmission Advisory Committee, working with outside experts, developed and disseminated to the community donor screening guidelines.[32] These initial guidelines will be continually updated and revised as clinical experience accumulates and technology and resources evolve. COVID-19 was added to the list of infections for mandatory reporting of potential donor-derived infections.

The OPTN data reported show the initial impact of the pandemic on transplantation broadly across the United States. There was a rapid decline in the number of deceased organ donors and transplants, with a near cessation of living donor kidney and liver transplantation. Overall deceased donor transplants decreased by approximately 50%. Lung transplants had the highest absolute decrease in transplant numbers. There was a decrease the number of transplants going to status 1 and 2 heart candidates, high LAS lung candidates, and high MELD/PELD liver candidates. This change was likely due to a desire to transplant recipients expected to have shorter hospital stays with less impact on the limited supply of intensive care beds in hospitals caring for large numbers of COVID-19 patients. Many transplant programs inactivated patients on their transplant waiting lists who were judged to have a less clinically urgent need for transplantation. There was an assumption, subsequently shown to be correct, that transplant recipients who acquire SARS-CoV-2 would have increased disease severity. Initial reports suggested mortality rates over 20% for transplant recipients with COVID-19.[33] These safety concerns were intensified by the initial lack of viral diagnostic testing resources for donor and recipient screening. In mid-March, there was a 40% decrease in deceased donors from approximately 260 to 163 deceased donors per week. In addition to the decline in the number of deceased donors, there were unanticipated challenges for organ placement due to the ability of transplant programs to accept organs because of hospital logistical limitations and limited commercial airline availability affecting transportation of kidneys.[34] The non-utilization rate of kidneys procured for transplantation transiently reached nearly 30% in late March but overall organ discard rates were little changed from pre-pandemic rates.

Although the impact of the pandemic at that time was most apparent in the Northwest and Northeast regions of the country, the decrease in deceased donors was observed broadly across the country. The gradual geographic spread of the pandemic allowed transplant centers not initially affected to put into place clinical resources and staffing to address anticipated impacts of the pandemic. This also allowed centers and OPOs to utilize changes in policy and procedures put in place by the OPTN to address the continued spread of the pandemic. The subsequent changes in transplant and donor numbers have been blunted and allowed the relatively rapid resumption of near normal clinical transplant activity.

Perhaps the most dramatic response to the pandemic within clinical transplantation was an abrupt near-cessation of living donor transplantation observed broadly across the country. Living donor kidney transplants decreased by over 90% during a 2-week period in March. Living donor liver transplants also decreased but, to a lesser degree, likely due to a greater medical urgency of liver recipients and a willingness to accept incompletely known COVID-19-associated risks.

Beginning in mid-March, there were significant numbers of waitlist patients who were placed in temporarily inactive status due to COVID-19 concerns. During the week of March 22, over 2,000 waitlist registrations were placed on inactive status due to COVID-19 concerns. This included concerns for patient safety but also included patient inactivation because of limitations on transplant programs' ability to perform transplant surgeries given decreased access to hospital resources, especially intensive care beds. In areas of the country particularly hard hit with COVID-19, there were large transplant programs that temporarily stopped all transplant activity. There was also a substantial decline in the number of new patients across all organ types being listed for transplantation. New patient listings decreased from approximately 1,400 per week at the beginning of March to 760 per week in the latter part of March. The decline in patients being added to transplant waitlists was likely a consequence of the widely observed decrease in the access to outpatient services required for evaluation of potential transplant recipients. OPTN data show that by April 21st all organ donors were being screened for COVID-19 and importantly no organs were procured from donors testing positive. The OPTN safety reporting system received a small number of reports of potential disease transmissions based on recipients testing positive soon after transplant but donor-derived disease transmission has not been confirmed. Aggressive monitoring of potential donor-derived disease transmission remains in place using the existing OPTN safety reporting systems.

As the COVID-19 pandemic continues to evolve and COVID-19 cases and COVID-19-related deaths accumulate, it appears that the impact of COVID-19 on the transplant system will not be a transitory event. There are certain to be long-lasting impacts on the transplant system and healthcare delivery. OPTN data show that by mid-May there was substantial recovery of donor and transplant numbers. Overall, organ utilization improved and transplants, both deceased and living donor, approached pre-pandemic levels. These observations suggest a resilient transplant system infrastructure that has adapted to a new clinical environment. Despite these national data observations, there continue to be regions of the country disproportionately affected by the pandemic. Because the pandemic has had different effects on different areas of the country at different times, the ability to assess transplant center and OPO performance in statistically valid ways using the conventional OPTN metrics is likely not possible for the foreseeable future, and has been recognized by the Scientific Registry of Transplant Recipients (SRTR). The SRTR has removed patient and donor data from calculated performance metrics for all transplants after March 12, 2020. The SRTR will continue to report descriptive data such as waitlist counts, donor counts, donor characteristics, and transplant numbers but expected outcomes for transplant centers and OPOs will not be calculated. This recognition will pose challenges for performance monitoring

and data collection going forward, and may ultimately accelerate the adoption of broader measures of transplant program and OPO performance.

There remains concern within the larger healthcare system, and in the transplant community, of adverse impacts of a continued pandemic and subsequent waves of SARS-CoV-2 infections. A successful response will require anticipatory policy responses and data collection and the incorporation of accumulated clinical experience into planning and resource allocation. The continued effective collaboration of the transplant community with its public partners and stakeholders should minimize the impacts of ongoing COVID-19 infections on the transplant system in the United States.

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DISCLOSURE

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

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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