Title
Early national and center-level changes to kidney transplantation in the United States during the COVID-19 epidemic

Journal
American Journal of Transplantation, 20(11)

ISSN
1600-6135

Authors
Boyarsky, Brian J
Werbel, William A
Durand, Christine M
et al.

Publication Date
2020-11-01

DOI
10.1111/ajt.16167

Peer reviewed

DR BRIAN J BOYARSKY (Orcid ID : 0000-0001-6902-9854)
DR WILLIAM A WERBEL (Orcid ID : 0000-0003-2943-5895)
DR CHRISTINE DURAND (Orcid ID : 0000-0003-2605-9257)
DR ROBIN K AVERY (Orcid ID : 0000-0001-7692-3619)
DR KYLE R JACKSON (Orcid ID : 0000-0002-8135-5377)
DR AMBER B KERNODLE (Orcid ID : 0000-0002-6459-5280)
DR JON J. SNYDER (Orcid ID : 0000-0001-7974-8940)
DR DORRY L SEGEV (Orcid ID : 0000-0003-3205-1024)
DR ALLAN B MASSIE (Orcid ID : 0000-0002-5288-5125)

Article type : Brief Communication

Brief Communication: Early National and Center-level Changes to Kidney Transplantation in the United States During COVID-19 Epidemic

Brian J. Boyarsky MD (1), William A. Werbel MD (2), Christine M. Durand MD (2), Robin K. Avery MD (2), Kyle R. Jackson MD PhD (1), Amber B. Kernodle MD MPH (1), Jon Snyder PhD (4), Ryutaro Hirose MD PhD (5), Indraneel M. Massie (6), Jacqueline M. Garonzik-Wang MD PhD (1), Dorry L. Segev MD PhD (1,3,4), Allan B. Massie PhD MHS (1,2)

(1) Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD
(2) Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
(3) Department of Epidemiology, Johns Hopkins School of Public Health, Baltimore, MD
(4) Scientific Registry of Transplant Recipients, Minneapolis, MN
(5) Department of Surgery, University of California, San Francisco, CA
(6) Oxford College of Emory University, Oxford, GA

Contact Information:

Allan Massie, Ph.D.

amassie1@jhmi.edu

ABBREVIATIONS

COVID-19: coronavirus disease 2020

KT: kidney transplant

LDKT: live donor kidney transplantation

DDKT: deceased donor transplantation

ESRD: end stage renal disease

DGF: delayed graft function

AKI: acute kidney injury

SRTR: Scientific Registry of Transplant Recipients

OPTN: Organ Procurement and Transplantation Network

HRSA: Health Resources and Services Administration

PMP: per million population

DCD: donation after circulatory death

IRR: incidence rate ratio

ICU: intensive care unit

OR: operating room

ABSTRACT

In March 2020, COVID-19 spread rapidly nationally, causing widespread emergent changes to the health system. Our goal was to understand the impact of the epidemic on kidney transplantation (KT), at both the national and center-levels, accounting statistically for waitlist composition. Using SRTR data, we compared data on observed waitlist registrations, waitlist mortality, living-donor and deceased-donor kidney transplants (LDKT/DDKT) March 15-April 30, 2020 to expected events calculated from pre-epidemic data January 2016-February 2020. There were few changes before March 15, at which point the number of new listings/DDKT/LDKT dropped to 18%/24%/87% below the expected value (all p<0.001). Only 12 centers performed LDKT March 15-31; by April 30, 40 centers had resumed LDKT. The decline in new listings and DDKT was greater among states with higher per capita confirmed COVID-19 cases. The number of waitlist deaths was 2.2-fold higher than expected in the five states with highest COVID-19 burden (p<0.001). DCD DDKT and regional/national imports declined nationwide, but most steeply in states with the highest COVID-19 burden. The COVID-19 epidemic has resulted in substantial changes to KT; we must adapt and learn rapidly to continue provide safe access to transplantation and limit the growing indirect toll of an already deadly disease.

INTRODUCTION

Since late December 2019, when a cluster of cases of pneumonia was reported in Wuhan, China, the spread of COVID-19 and subsequent effects on the world's health care systems have been explosive and wide-ranging (1). The effects have varied by region, as have the responses to the epidemic, with certain countries and areas reacting with strict shelter-in-place orders, and others observing a rapid escalation of cases and deaths due to SARS-CoV-2. In some states, health care resources have been stretched thin and overwhelmed with the number of cases outstripping the number of hospital beds and intensive care resources. Organ transplantation is a resource intensive endeavor, and thus the potential effects of the epidemic on transplantation in the United States are profound.

COVID-19 has impacted virtually all aspects of kidney transplantation (KT) (2-9), affecting the donor supply and both candidates and recipients (10-13). Early reports demonstrate variable severity in patients with end stage renal disease (ESRD) and KT, ranging from asymptomatic to fulminant respiratory failure and death (14). Furthermore, COVID-19 has been associated with acute kidney injury (AKI), which may predispose KT recipients to increased morbidity (15-17). Previous experience with related viruses, SARS-CoV in 2003 (18), and MERS-CoV in 2015 (19), demonstrated that immunosuppressed KT recipients may be anticipated to have prolonged viral shedding, potentially increasing transmissibility, morbidity, and mortality (7, 20).

In a national survey of US transplant centers in the last week of March 2020, 72% of centers reported that they had suspended LDKT and 84% reported restrictions to DDKT; more stringent restrictions were associated with higher regional incidence of COVID-19 (21). Restrictions varied by center; for example, some centers reported transplanting highly sensitized patients and those without dialysis access, whereas others reported transplanting those with the lowest risk of delayed graft function (DGF), prolonged hospital stay, or readmission.

These actions were taken in the context of immense uncertainty, during an epidemic that was one point doubling every two days, and in the context of an emergency national diversion of hospital resources to address the anticipated burden of COVID-19 on the medical system. However, simulation data suggest that even a temporary suspension of KT may lead to greater risk of death for waitlist registrants (22). The early effect of the epidemic on access to KT in the United States has not been quantified. Given the variation in incidence of COVID-19 across the US, limited knowledge about COVID-19 prevalence among the general population, and ongoing diversion of healthcare resources, we hypothesized that COVID-19's impact on KT might also be center-dependent and associated with geographic incidence of COVID-19.

To address this knowledge gap, using data from the SRTR, we conducted a retrospective study of changes to KT waitlist registration, waitlist deaths, and rates of DDKT and LDKT March-April 2020. We examined rates of these waitlist events among the overall patient population and among key patient subgroups and stratified by state-level burden of COVID-19 infection.

METHODS

Data Source

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere (23). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

State-level cumulative incidence of COVID-19 per million population

To examine the relationship between COVID-19 burden and waitlist events (new listings, DDKT, and deaths), we calculated cumulative incidence of reported COVID-19 cases per million population (PMP) at the state level (including the District of Columbia and Puerto Rico) on March 25, 2020, using data from http://covidtracking.com/ . States were classified by COVID-19 burden as "low" (<50 cases PMP: 13 states); "medium" (50-100 cases PMP: 15 states); "high" (100-300 cases PMP: 15 states); and "very high" (300-1584 cases PMP: Louisiana, Michigan, New Jersey, New York, and Washington state).

Daily counts of waitlist changes

For each day between February 1 and April 30, 2020, we plotted daily counts of new waitlist registrations, newly inactive patients, and waitlist removals due to DDKT, LDKT, death, or deteriorating condition, with a

Lowess smooth. For new waitlist registrations, LDKT, and newly inactive registrants, only weekdays were included, since between January 2016 and February 2020 >98.5% of these events occurred on weekdays. We made similar plots for daily counts of donation after circulatory death (DCD), DDKT, and regional and national imports. Since LDKT decreased abruptly after March 15, we plotted of center-level counts of LDKT between March 15-April 30, 2020 by state-level cumulative incidence of COVID-19 PMP.

Calculating center-level expected numbers of waitlist events

A raw count of center-level waitlist events fails to take into account potential differences in a center's waitlist population over time. To address this, for each of the waitlist events described above, we modeled the number of outcomes per center per month between January 2016 and February 2020 using multilevel Poisson regression, with a center-level random intercept and adjusting for center-level distribution of candidate characteristics: age, sex, prior transplant, race/ethnicity, history of diabetes, insurance type, time on dialysis, and ABO blood type. We then used these models to predict the expected number of outcomes per month in March-April 2020. We made these predictions overall and for subgroups of patients based on candidate characteristics.

Comparing observed to expected center-level numbers of waitlist events

For each type of waitlist event, we compared observed to expected counts using χ^2 tests, overall and for various patient subgroups. Additionally, to compare differences in observed vs expected events among centers in states with different levels of COVID-19 burden, we used Poisson regression. Specifically, we modeled the observed counts, including the log of expected counts in the model with the coefficient constrained to one, and adjusting for state-level COVID-19 burden. The incidence rate ratios (IRRs) from this model represent the observed counts as a proportion of expected counts.

Statistical analysis

Confidence intervals are reported as per the method of Louis and Zeger (24). All analyses were performed using Stata 16.1/MP for Linux (College Station, Texas).

RESULTS

Daily counts of waitlist changes

Between February 1-March 1 2020, on average there were 168 new registrations per weekday; this declined to 158 per weekday by April 1 and 107 on May 1 (Figure 1A). The number of newly inactive patients averaged 102 per weekday from February 1 to mid-March, before climbing to 385 per day in the week of March 23-27, and 192 per day between April 1-15 (Figure 1B). There is an odd spike because one center changed its entire waitlist to inactive on April 23 and then back to active on April 30.

The proportion of the waitlist that was inactive rose gradually from 36.7% on February 1 to 37.1% on March 15, to 40.4% by April 2, and 40.5% by May 1 (Figure 1C).

The number of waitlist removals due to death and deteriorating condition averaged 9.3 and 12.5 per day, respectively (Figure 2A, 2B).

The number of DDKT averaged 51 per day; this number declined from 47 on March 15 to 29 on April 1, and was 53 on May 1 (Figure 3A). The number of DCD DDKT declined from 12 on March 15 to 3 on April 1 and 3 on May 1 (Figure 3B). The number of regional and national imports declined over the same interval (Figures 3C, 3D).

The average number of LDKT per day declined sharply after March 15 (Figure 4A). Only twelve centers performed LDKT between March 15-March 31, of which only six performed more than two LDKTs. Between March 15-April 30, 40 centers performed LDKT, of which 12 performed more than two LDKTs. None of the 40 centers were in states with more than 300 COVID-19 cases PMP (Figure 4B).

Comparing observed to expected counts of waitlist events

Overall, the observed number of DDKT between March 15-April 30 (1673) was 23.9% lower than the expected number (2197.8), a statistically significant difference ($p<0.001$) (Table 2). Similarly, the observed number of LDKT (114) was 87.2% lower than expected (888.2, $p<0.001$) (Table 3). The observed number of waitlist deaths (453) was 6.5% higher than expected (425.3, $p=0.2$) (Table 4).

The center-level observed number of new listings, DDKT, and LDKT March 15-April 30 was lower than the expected number across all categories of COVID-19 burden (Table 1A). Among centers in states with low COVID-19 rates, there were 9% fewer new listings than expected (IRR $_{0.85}$ 0.91 $_{0.96}$). The proportional drop in new listings was steeper at centers in states with higher COVID-19 rates (e.g. IRR in "very high" states=$_{0.54}$ 0.59 $_{0.64}$). Similarly, the IRR for observed vs expected DDKT ranged from $_{0.72}$ 0.79 $_{0.87}$ in states with low COVID-19 rates to $_{0.33}$ 0.39 $_{0.46}$ in states with very high COVID-19 rates. Among centers in states with low COVID-19 rates, there were 84% fewer LDKT than expected (IRR=$_{0.11}$ 0.16 $_{0.23}$); among centers in states with very high COVID-19 rates, there were 99% fewer LDKT than expected (IRR=$_{0.00}$ 0.01 $_{0.05}$). Centers in states with very high COVID-19 rates which had 2.2-fold more waitlist deaths than expected (IRR=$_{1.88}$ 2.22 $_{2.62}$). The decline in DDKT was greatest among patients over the age of 50 (e.g. for age 70+, 78 observed vs 145.9 expected) (Table 2).

The number of DCD DDKT March 15-April 30 was lower than expected across all categories of COVID-19 burden, with the IRR ranging from $_{0.50}$ 0.62 $_{0.76}$ in states with low COVID-19 rates to $_{0.14}$ 0.21 $_{0.33}$ at centers in states with very high COVID-19 rates (Table 1B). Regional and national imports also declined at centers in states with very high COVID-19 rates (IRR=$_{0.14}$ 0.26 $_{0.48}$ and $_{0.16}$ 0.25 $_{0.38}$, respectively).

DISCUSSION

In this national registry study of KT waitlist registrations, waitlist mortality, and rates of transplantation using data from the SRTR in the early COVID-19 era, we found the number of new registrations dropped by 18% below expected, DDKT dropped 24% below expected, and LDKT virtually came to a standstill. Additionally, we found that, though the number of waitlist deaths nationwide was not significantly higher than expected, it was 2.2-fold higher than expected in the five states with highest COVID-19 burden. There was substantial geographic heterogeneity, as these drops were greater among the states with highest COVID-19 incidence. These findings represent the dramatic impact of COVID-19 on KT; ongoing data collection and reporting are critical to continue to provide safe access to transplantation and limit the indirect downstream effects of this deadly disease.

COVID-19 is a novel disease and we are learning more about its impact on KT in real-time. Therefore, early and frequent reporting on waitlist registrations, removals, and rates of KT is necessary to inform evolving clinical practices.

Our findings of decreased waitlist registrations coupled with increased waitlist inactivations are consistent with findings from our national survey in which we reported reduction in transplant activity (21). The dramatic reduction in DCD KT may be reflective of limited hospital beds, limited ventilators, and limited access to intensive care units (ICUs) and operating rooms (ORs); centers may be seeking to avoid the short-term complications (e.g. DGF and longer hospital stay) that can result from DCD DDKT (26, 27). Our finding of a virtual halt of LDKT is also consistent with our survey in which we found that early in the epidemic, 72% of centers had suspended LDKT, and is likely reflective of center-level priority for urgent or emergent operations. Our findings that most of the drops in activity were heightened in areas of high COVID-19 incidence is consistent with reports of diversion of healthcare resources.

Since waitlist deaths which occur outside of the transplant center may not be reported immediately to the transplant center and then to the OPTN, it is possible that this delay may have caused us to undercount total deaths in March and April 2020. However, the difference in waitlist mortality stratified by COVID-19 incidence is striking, and unlikely to be confounded by reporting delay. In fact, if there were a delay, the apparent increase we saw in waitlist mortality in the high-incidence states may be even higher than reported. Though our results did not demonstrate major differences in changes to listing in the COVID-19 era based on race/ethnicity or insurance status, additional studies will be necessary to help inform the extent to which vulnerable transplant candidates were and are particularly impacted by the epidemic (25).

This study must be understood in the context of its limitations. National transplant registry data are captured by centers across the United States, which may have varying reporting standards and quality control. Additionally, our use of national registry data precludes assessment of key questions such as why a particular patient became inactive on the waitlist, or cause of death information. Despite this limitation, our use of national registry data facilitates broadly generalizable inferences, especially in the context of linking data to state-level COVID-19 incidence rates. Furthermore, given the rapidly changing nature of the epidemic and limits on data availability, we limited our observed data to the last two weeks of March and the month of

April, which may have underestimated the true rates of waitlist registrations, removals, and KT. These differences may only become apparent with additional data collection and analysis. Finally, there was lack of information on true incidence of COVID-19 due to significant variations and gaps in testing capacity that was especially apparent during this early window in the epidemic; this may have led us to misclassify some states with high COVID-19 burden but poor testing capacity. Nonetheless, even without comprehensive incidence and testing data, we were able to capture an increase in all-cause mortality in states with the highest reported COVID-19 incidence, even without testing data specific to waitlist registrants.

In summary, we found that in the early COVID-19 era in the US, access to KT has been substantially limited as evidenced by decreased waitlist registrations, increased waitlist mortality increased in states with highest COVID-19 burden, decreased DDKT, and a virtual standstill in LDKT. These findings suggest that the epidemic has had a major impact on the KT population in the United States; we must be vigilant and learn and evolve rapidly to inform transplant practices and safely facilitate a reboot of KT.

ACKNOWLEDGEMENTS

This work was supported by grant number T32DK007713 (Boyarsky), T32AI007291 (Werbel), F32DK113719 (Jackson), F32DK117563 (Kernodle), K24DK101828 (Segev) and K01DK101677 (Massie) from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. The analyses described here are the responsibility of the authors alone and do not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products or organizations imply endorsement by the U.S. Government. The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government.

DISCLOSURE

The authors of this manuscript 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 available from the Scientific Registry of Transplant Recipients (SRTR). Restrictions apply to the availability of these data, which were used under license for this study. Data are available the corresponding author with the permission of the SRTR.

Table 1. Observed center-level events as a proportion of expected events, March 15-April 30, 2020.

Centers in states with the lowest rates of per capita reported COVID-19 cases had 9% fewer new listings than expected (IRR=0.91), 21% fewer DDKT (IRR 0.79), 84% fewer LDKT (IRR 0.16), and 23% fewer waitlist deaths (IRR=0.77, NS). Centers in states with very high rates of COVID-19 cases had 41% fewer new listings than expected, 61% fewer DDKT, 99% fewer LDKT, and 2.2-fold more waitlist deaths. **Bold** denotes IRRs that are statistically significantly different from the IRR in states with the lowest per-capita reported COVID-19 cases.

A

COVID-19 rates	New listings	DDKT	LDKT	Waitlist death
Overall	$_{0.80}$ 0.82 $_{0.84}$	$_{0.73}$ 0.76 $_{0.80}$	$_{0.11}$ 0.13 $_{0.15}$	$_{0.97}$ 1.07 $_{1.17}$
Low (NC/TX/VA+10)	$_{0.85}$ 0.91 $_{0.96}$	$_{0.72}$ 0.79 $_{0.87}$	$_{0.11}$ 0.16 $_{0.23}$	$_{0.59}$ 0.77 $_{1.00}$
Medium (CA/FL/PA+12)	$_{0.84}$ 0.87 $_{0.91}$	**$_{0.87}$ 0.93 $_{0.99}$**	$_{0.13}$ 0.17 $_{0.22}$	$_{0.70}$ 0.81 $_{0.95}$
High (IL/MA/TN+12)	**$_{0.74}$ 0.79 $_{0.85}$**	**$_{0.58}$ 0.66 $_{0.74}$**	$_{0.08}$ 0.11 $_{0.17}$	$_{0.86}$ 1.05 $_{1.29}$
Very high (LA/MI/NJ/NY/WA)	**$_{0.54}$ 0.59 $_{0.64}$**	**$_{0.33}$ 0.39 $_{0.46}$**	**$_{0.00}$ 0.01 $_{0.05}$**	**$_{1.88}$ 2.22 $_{2.62}$**

B

COVID-19 rates	DCD DDKT	Regional import	National import
Low (NC/TX/VA+10)	$_{0.50}$ 0.62 $_{0.76}$	$_{0.66}$ 0.82 $_{1.03}$	$_{0.68}$ 0.90 $_{1.18}$
Medium (CA/FL/PA+12)	**$_{0.77}$ 0.88 $_{1.01}$**	$_{0.89}$ 1.03 $_{1.19}$	$_{0.63}$ 0.76 $_{0.91}$
High (IL/MA/TN+12)	$_{0.36}$ 0.47 $_{0.61}$	$_{0.61}$ 0.81 $_{1.08}$	$_{0.62}$ 0.84 $_{1.14}$
Very high (LA/MI/NJ/NY/WA)	**$_{0.14}$ 0.21 $_{0.33}$**	**$_{0.14}$ 0.26 $_{0.48}$**	**$_{0.16}$ 0.25 $_{0.38}$**

Table 2. Observed and expected DDKT counts, March 15-April 30, 2020.

Category	Expected	Observed	% change	p
Overall	2197.8	1673	-23.9	<0.001
Age: 0-11	25.5	11	-56.9	
Age: 12-17	34.9	26	-25.5	
Age: 18-29	135.5	144	6.3	
Age: 30-39	260.6	236	-9.4	<0.001
Age: 40-49	431.4	360	-16.6	
Age: 50-59	602.7	443	-26.5	
Age: 60-69	580.0	375	-35.3	
Age: 70+	145.9	78	-46.5	
Prior tx: no	1911.1	1480	-22.6	0.4
Prior tx: yes	274.6	193	-29.7	
Race/ethnicity: white	827.9	596	-28.0	
Race/ethnicity: black	717.5	569	-20.7	
Race/ethnicity: Hispanic	436.8	344	-21.2	0.7
Race/ethnicity: Asian	159.8	123	-23.0	
Race/ethnicity: other nonwhite	52.0	41	-21.2	
DM: no	1368.7	1056	-22.8	0.7
DM: yes	831.6	616	-25.9	
Pay: private	799.3	687	-14.0	
Pay: Medicaid	207.6	144	-30.6	
Pay: Medicare	1073.8	769	-28.4	<0.001
Pay: Other pub	25.6	25	-2.3	

Pay: Other	69.3	29	-58.2	
Male	1331.7	1078	-19.1	<0.01
Female	862.5	595	-31.0	

Table 3. Observed and expected LDKT counts, March 15-April 30, 2020.

Category	Expected	Observed	% change	p
Overall	888.2	114	-87.2	<0.001
Age: 0-11	13.9	4	-71.2	
Age: 12-17	11.6	1	-91.4	
Age: 18-29	93.6	9	-90.4	
Age: 30-39	125.8	13	-89.7	0.2
Age: 40-49	171.8	29	-83.1	
Age: 50-59	212.9	30	-85.9	
Age: 60-69	189.2	25	-86.8	
Age: 70+	68.7	3	-95.6	
Prior tx: no	790.3	103	-87.0	>0.9
Prior tx: yes	90.7	11	-87.9	
Race/ethnicity: white	563.1	74	-86.9	
Race/ethnicity: black	115.7	14	-87.9	
Race/ethnicity: Hispanic	130.3	15	-88.5	0.5
Race/ethnicity: Asian	55.3	11	-80.1	
Race/ethnicity: other nonwhite	15.3	0	-100.0	
DM: no	627.5	79	-87.4	>0.9
DM: yes	259.5	35	-86.5	
Pay: private	532.7	76	-85.7	
Pay: Medicaid	56.3	6	-89.3	
Pay: Medicare	250.5	26	-89.6	0.7
Pay: Other pub	4.7	0	-100.0	

Pay: Other	41.8	4	-90.4	
Male	552.2	78	-85.9	0.4
Female	330.0	36	-89.1	

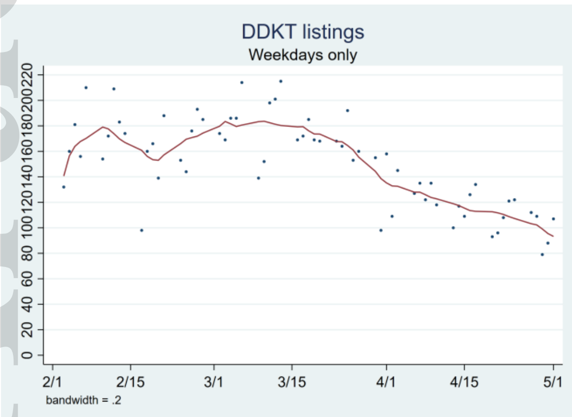
Table 4. Observed and kidney waitlist deaths, March 15-April 30, 2020.

Category	Expected	Observed	% change	p
Overall	425.3	453	6.5	0.2
Age: 0-11	0.4	2	400.0	
Age: 12-17	1.6	2	25.0	
Age: 18-29	10.2	7	-31.4	
Age: 30-39	25.1	30	19.5	0.03
Age: 40-49	71.5	71	-0.7	
Age: 50-59	129.2	161	24.6	
Age: 60-69	155.1	143	-7.8	
Age: 70+	29.3	37	26.3	
Prior tx: no	353.6	386	9.2	0.7
Prior tx: yes	69.3	67	-3.3	
Race/ethnicity: white	179.9	167	-7.2	
Race/ethnicity: black	123.8	152	22.8	
Race/ethnicity: Hispanic	78.0	82	5.1	0.2
Race/ethnicity: Asian	32.1	42	30.8	
Race/ethnicity: other nonwhite	9.5	10	5.3	
DM: no	153.4	161	5.0	0.9
DM: yes	267.1	291	8.9	
Pay: private	157.5	171	8.6	
Pay: Medicaid	32.3	61	88.9	
Pay: Medicare	219.1	212	-3.2	<0.001
Pay: Other pub	5.6	4	-28.6	

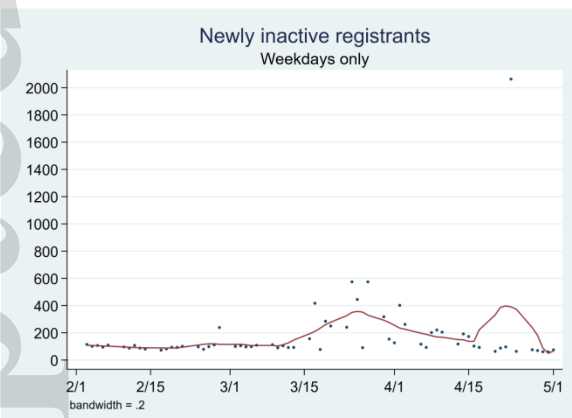
Pay: Other	8.7	3	-65.5	
Male	266.3	316	18.7	0.01
Female	156.8	137	-12.6	

Figure 1. KT waitlist registrations and active status, February-April 2020. Counts of new DDKT waitlist registrations (1A) and patients moved to inactive status (1B) per day, with Lowess smooth; (1C) proportion of prevalent waitlist list listed as inactive per day.

A



B



C

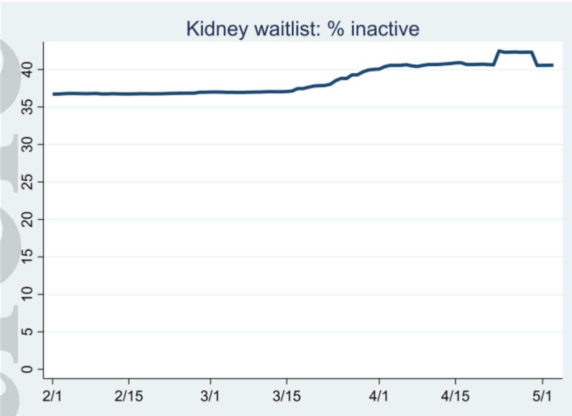
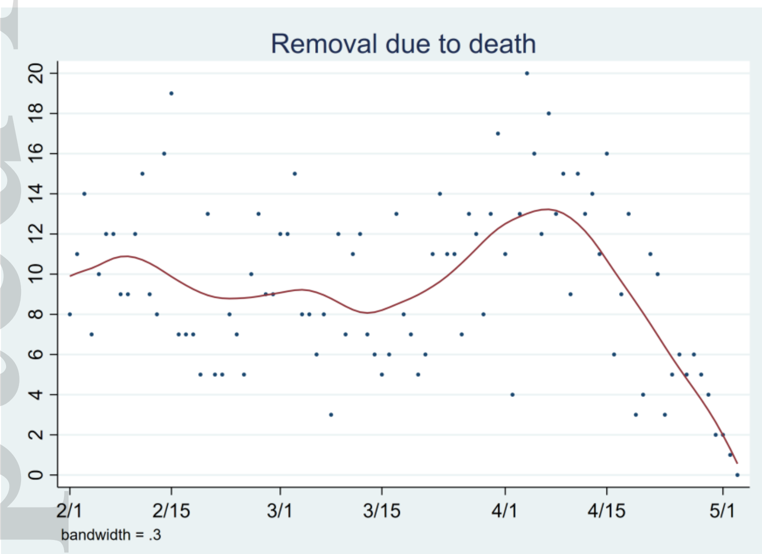


Figure 2. Counts of KT waitlist outcomes per day, February-April 2020, with Lowess smooth. (2A) removals due to death; (2B) removals due to deteriorating condition.

A



B

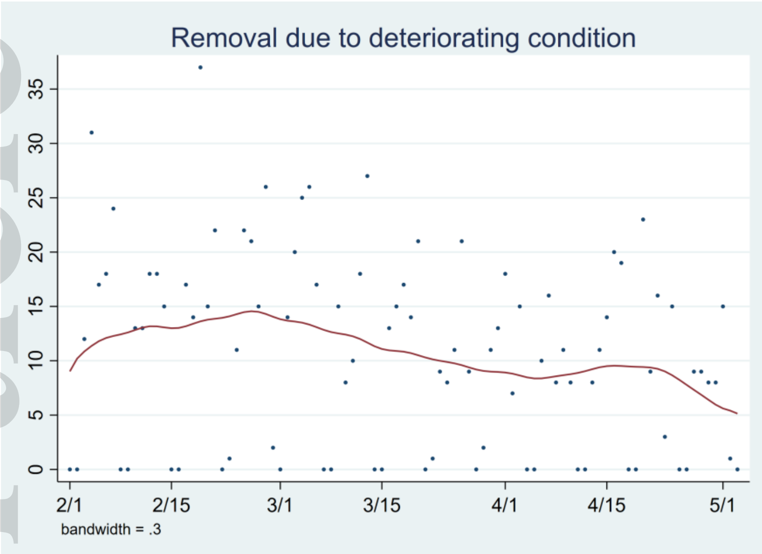

Removal due to deteriorating condition
0
5
10
15
20
25
30
35
2/1
2/15
3/1
3/15
4/1
4/15
5/1
bandwidth = .3

Figure 3. Counts of DDKT per day, February-April 2020, with Lowess smooth. (3A) all DDKT; (3B) DCD; (3C) regional imports; (3D) national imports.

A **B**

C **D**

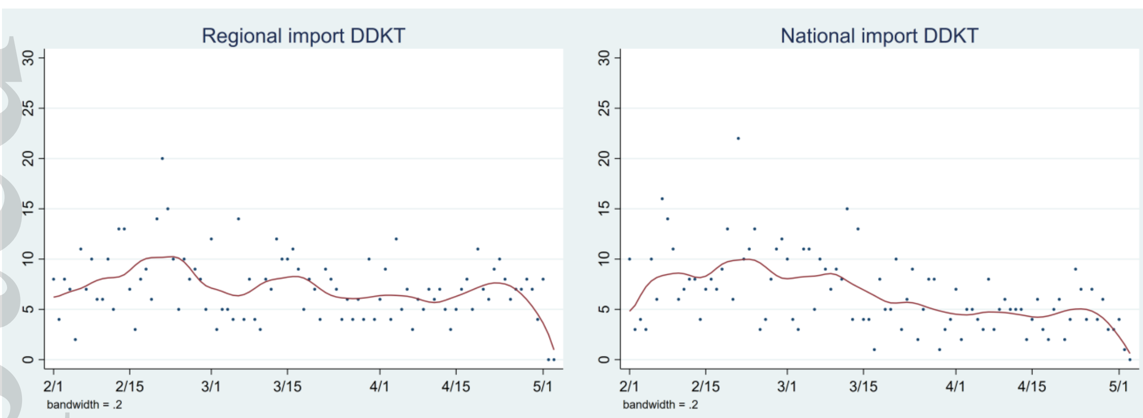
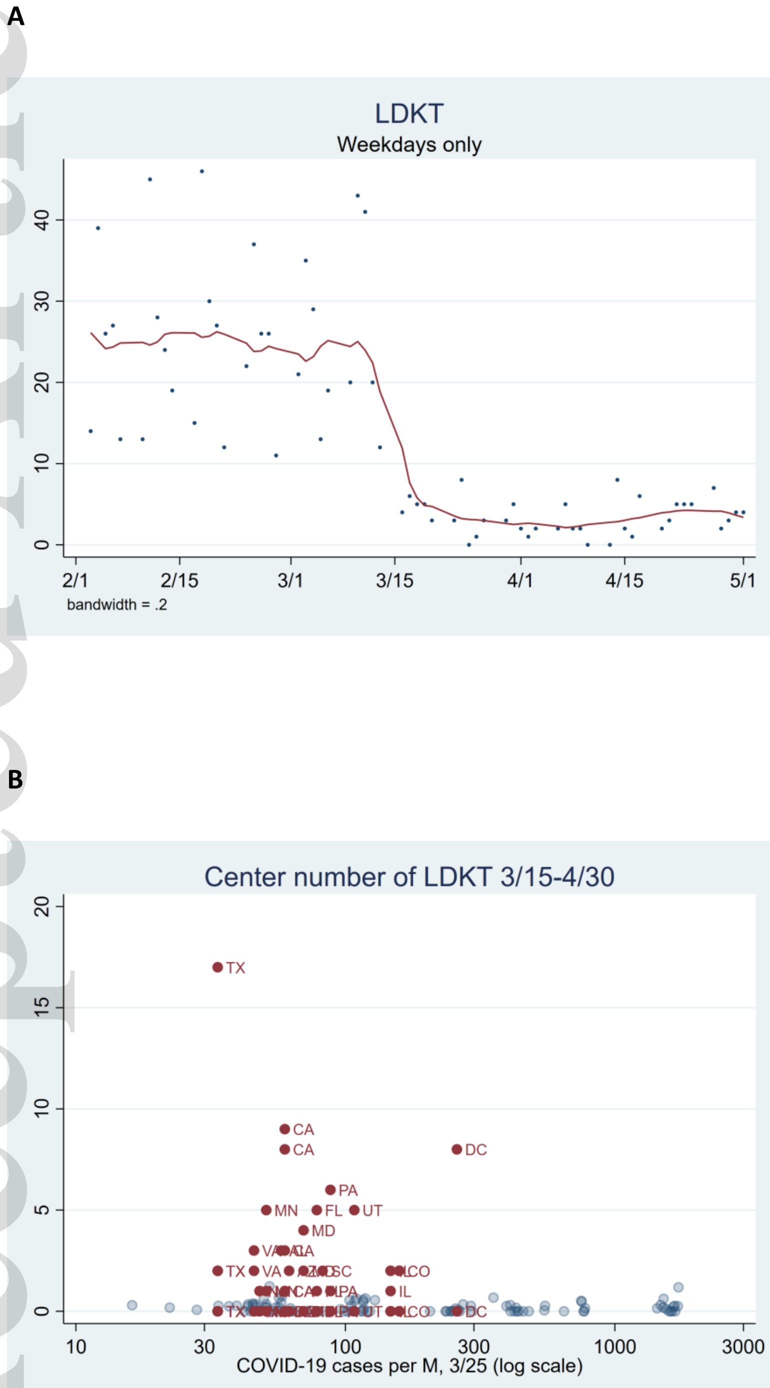


Figure 4. LDKT, February-April 2020. (4A) Counts of LDKT per day, February-March 2020, with Lowess smooth. (4B) Center-level LDKT, February-April, 2020, by COVID-19 prevalence per million population. Centers from states where more than one LDKT was performed are marked in dark red.



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