



T R A C I E

HEALTHCARE EMERGENCY PREPAREDNESS
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Healthcare Operations during the COVID-19 Pandemic- Speaker Series

March 2022

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Impact of COVID-19 on Solid Organ Donation and Transplantation: OPTN Responses

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March 2022

Acknowledgments and Disclosures

- This work was supported wholly or in part by the HRSA contract 250-2019-00001C. The content is the responsibilities of the author alone and does not necessarily reflect the views or policies of the Department of HHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.
- I have no disclosures

National Organ Transplant Act of 1984

- Organ Procurement & Transplantation Network (OPTN)
 - Private nonprofit entity by contract with HHS
 - Establish membership criteria and medical criteria for allocating organs
 - National policy and system; nationwide coordination
 - Original scope recommended by 1986 task force
 - Original enforcement authority not clearly defined
- Created the modern OPO system
- Created SRTR for data analysis

Key OPTN responsibilities

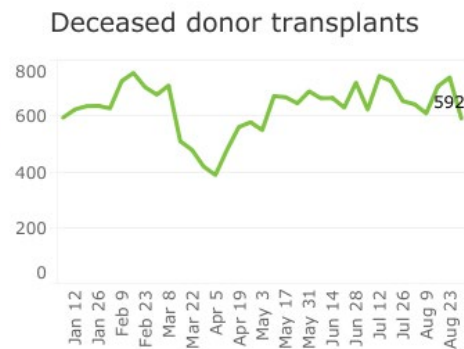
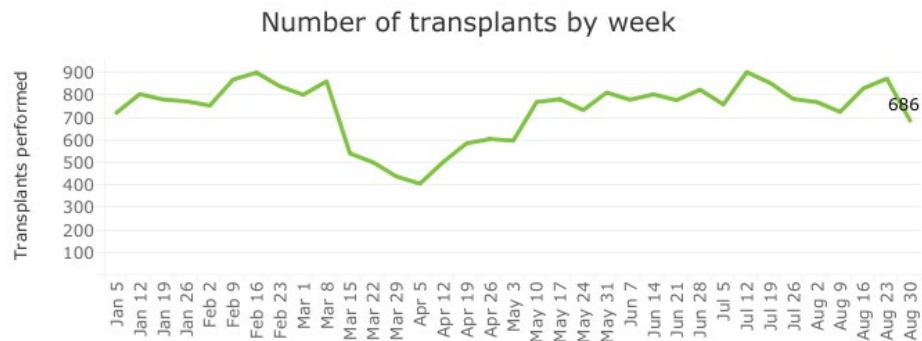
- Maintain national transplant lists
- Matches available organs with recipients
- Facilitate organ distribution, transplantation
- Establish equitable policies and membership standards
- Monitor members for compliance, safety, quality
- Collect/validate/report transplant data

OPTN is a Membership Organization

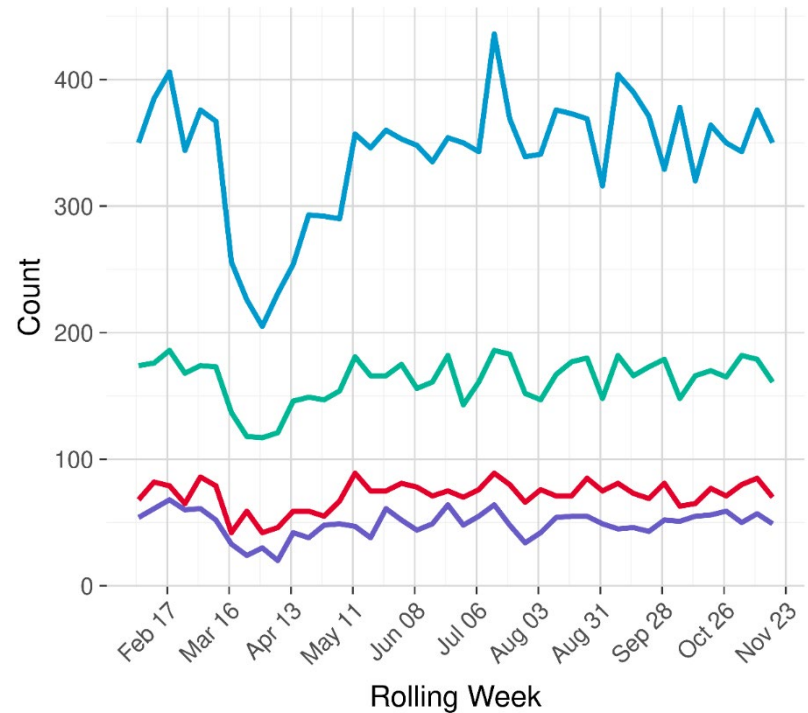
As of March 2022

Transplant Hospitals	251
Organ Procurement Orgs.	57
Histocompatibility Labs	141
Public Orgs.	7
Medical/Scientific Orgs.	10
Individual Members	7

COVID-19 Impact on Transplantation

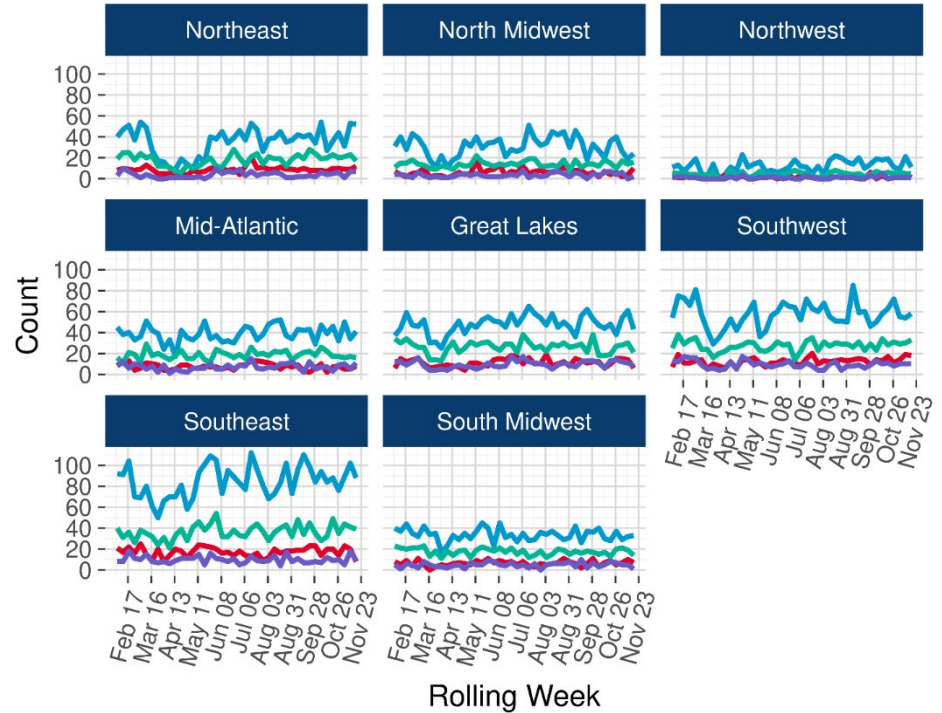


Deceased Donor Transplants by Week, Geography, and Organ Type



— Kidney — Heart — Liver — Lung

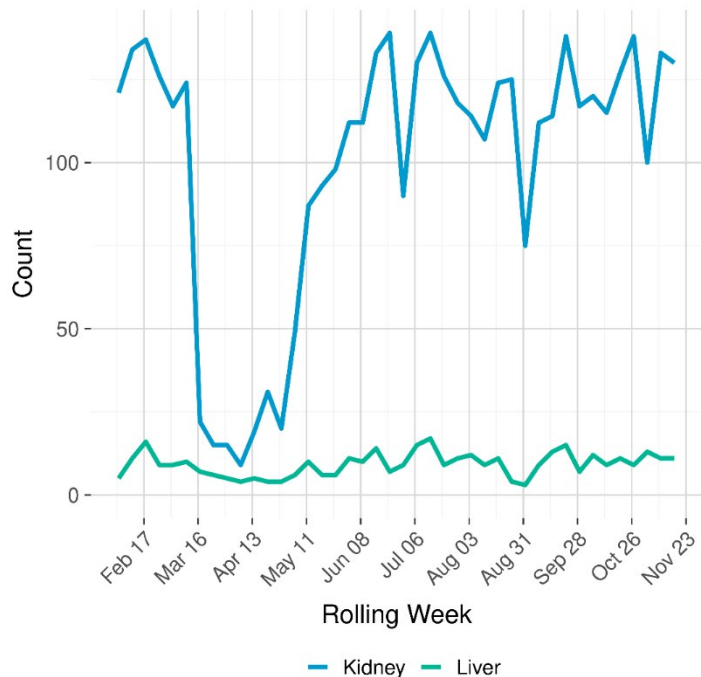
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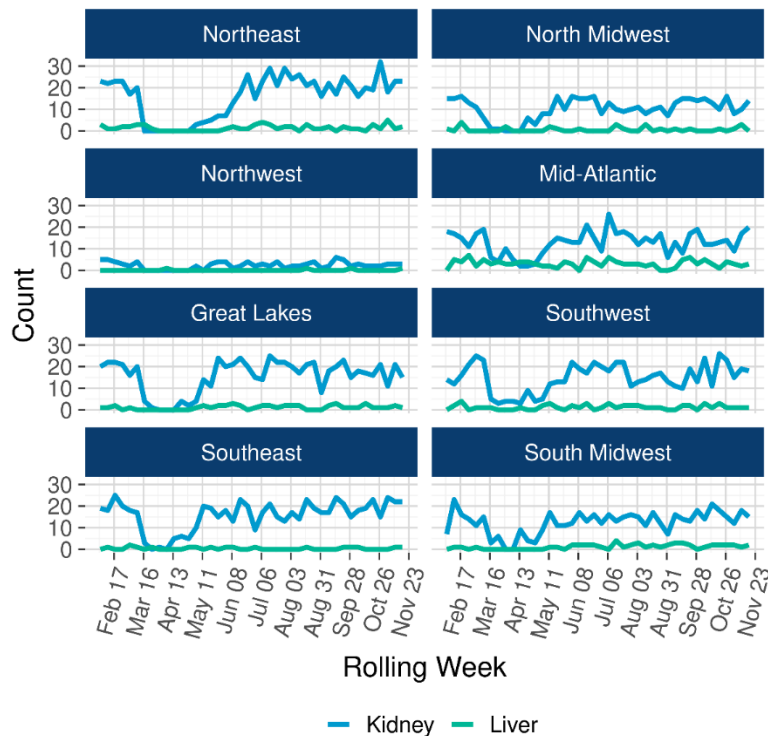
— Kidney — Heart — Liver — Lung

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Living Donor Transplants by Week, Geography, and Organ Type

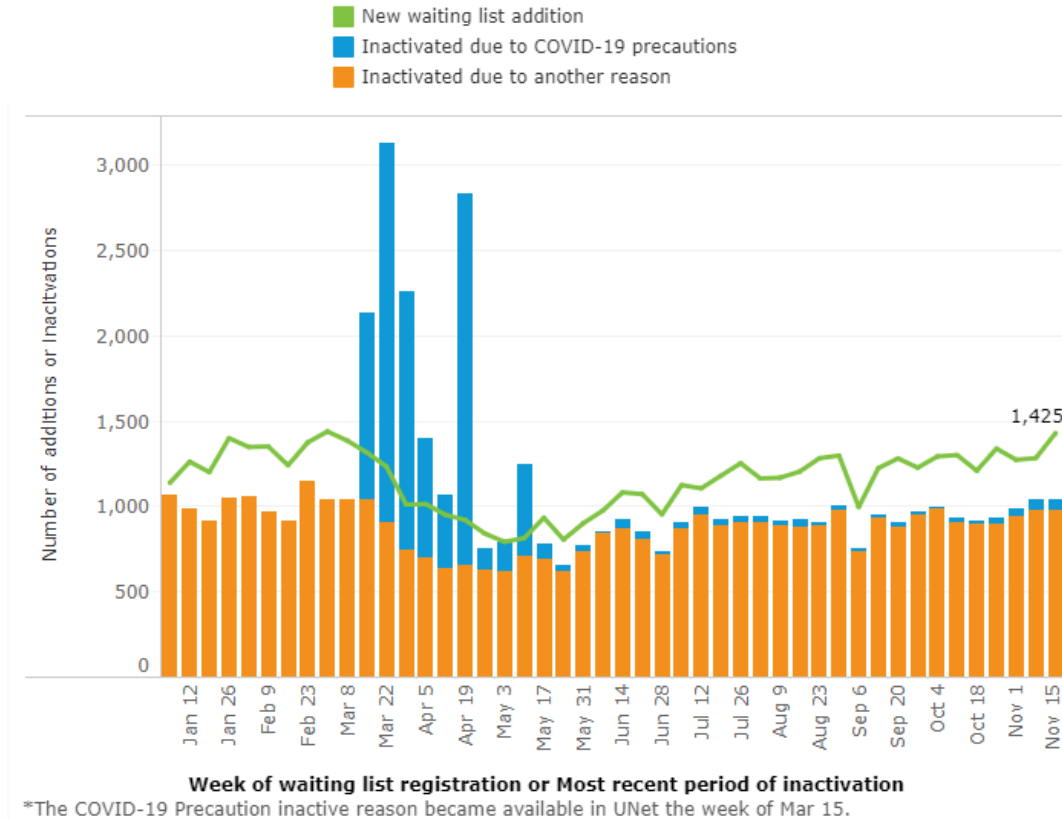


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Waiting List Additions and Inactivations by Week



Operational Actions in Response to COVID-19

- Move to virtual!
 - Regional meetings
 - Committees/Board
 - Site surveys
- Collaborative website launched to support community
- Weekly monitoring report developed for HRSA
- Daily reporting to HRSA on media activity
- Resources on OPTN website
- Emergency policy actions taken by executive committee

OPTN Emergency Actions in Response to Community COVID-19 Related Concerns

Emergency action	Approval date	Current expiration date
Updates to Candidate Data During 2020 COVID-19 Emergency	March 17, 2020	March 17, 2021
Relax Data Submission Requirements for Follow-Up Forms	April 3, 2020	December 31, 2020
Modify Wait Time Initiation for Non-Dialysis Kidney Candidates	April 3, 2020	December 31, 2020
Incorporate COVID-19 Infectious Disease Testing into DonorNet®	April 3, 2020	December 31, 2020

Rationale

- Reduce candidate, recipient, and living donor exposure to COVID-19
- Reduce transplant hospital burden during pandemic
- Prevent disadvantaging candidates who are unable to safely access the hospital for pre-transplant lab testing
- Provide OPOs and transplant hospitals efficient communication of COVID-19 testing status and results

Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency

- Programs can use a candidate's most recently submitted lab data to maintain medical urgent allocation priority
- Discretion on when to use emergency policy versus bring in a candidate for updated labs left to individual programs
- Primary usage was adult lung, followed by adult liver
- Backdated to declaration of national emergency on March 13, 2020

Action 2: Relax Data Submission Requirements for Follow-Up Forms

- Applies to organ-specific Transplant Recipient Follow-Up (TRF), Living Donor Follow-Up (LDF), and Post-Transplant Malignancy (PTM) forms
- The timeline to report recipient graft failure or death was extended from 14 to 30 days
- If TRF, LDF, or PTM forms are not submitted by their expected date, they are automatically marked in “amnesty” status
- “Amnesty” status implemented April 13, 2020
- Data can still be updated after forms enter amnesty status

Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates

- Allows programs to request the initiation of waiting time for non-dialysis kidney candidates to be backdated to the date the program intended to list the candidate for transplant
- Intended to keep candidates from being disadvantaged if they are delayed in completing all required labs for registration
- Modification request form implemented April 10, 2020

Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®

- Added an optional field to DonorNet to report COVID-19 testing, test type, specimen type, and result
- Implemented April 20, 2020
- Proposed as an optional field for quicker implementation, as well as to minimize disruption to allocation workflow
- 100% of recovered deceased donors have been tested for COVID-19 between April 21, 2020 and September 1, 2020, although only about 75% used the discrete infectious disease testing fields

Additional Emergency Policy

On May 27, 2021, the OPTN implemented an emergency policy requiring lower respiratory testing (LRT) by nucleic acid test (NAT) for SARS-CoV-2 for all potential deceased lung donors. Test results must be available prior to lung transplant.

The DTAC developed this policy in response to evidence that upper respiratory testing alone poses a patient safety risk to lung recipients.

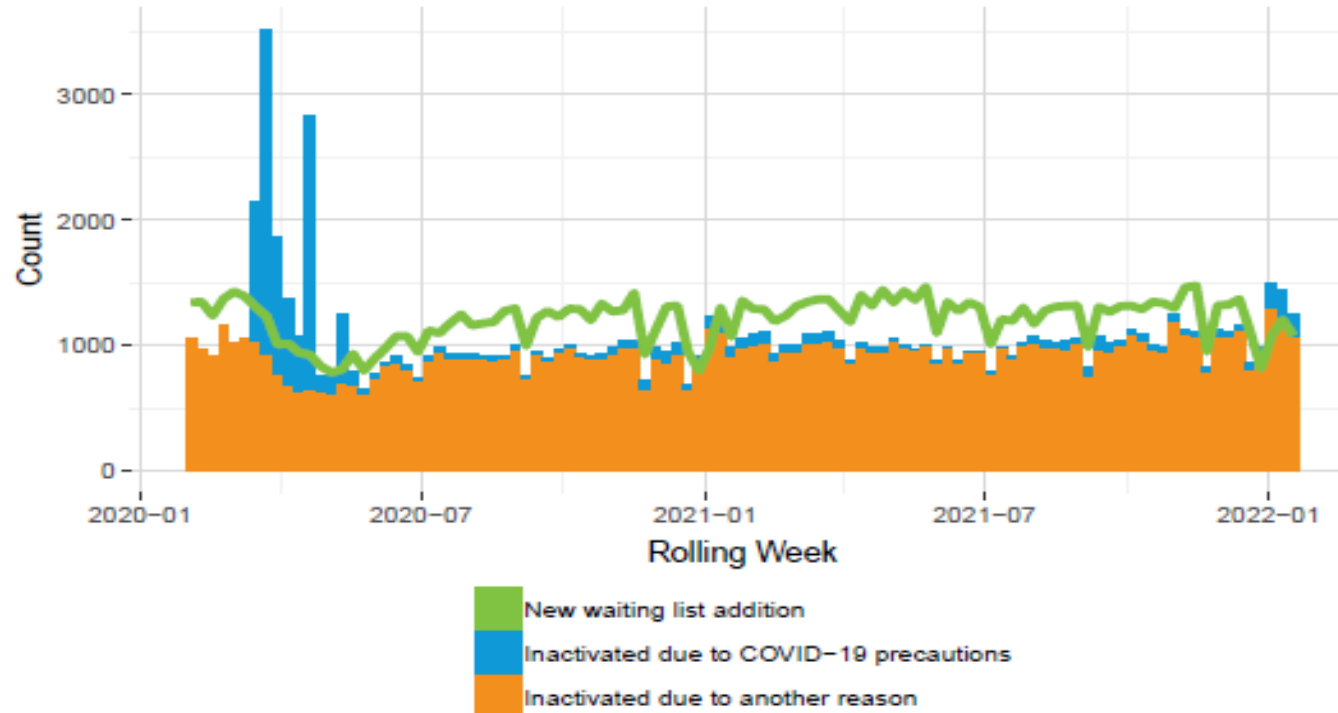
- 4 cases over a 3-month period (Dec 2020 – Feb 2021) in which a deceased lung donor tested negative for COVID-19 by upper respiratory specimen, then retrospectively tested positive by lower respiratory specimen.

COVID-Related Policy Status

Policy	Status
Updating Candidate Data During COVID-19 Emergency	Repealed April 26, 2021, effective July 27, 2021 .
Relax Data Submission Requirements for Follow-up Forms (“amnesty policy”)	Repealed March 1, 2021; forms due March 13, 2020 through March 31, 2021 due July 1, 2021
Modify Wait Time Initiation for Non-Dialysis Kidney Candidates	Repealed June 14, 2021, effective September 1, 2021 .
Incorporate COVID-19 Infectious Disease Testing into DonorNet®	Permanent and required – implementation date January, 27, 2021
Lower Respiratory SARS-CoV-2 Testing for Lung Donors	Emergency and required – implementation date May 27, 2021

COVID Data

Waitlist additions and inactivations



1 day lag applied

Effective Practices

- Provide a central site for real-time data dashboards and resources
- Frequent and regular communication with members
- Collaborative website for OPTN members to communicate
- Rapid policy change using defined emergency pathway to address member challenges
- Rapid incorporation and assessment of new data elements
- Daily communication to government partner HRSA

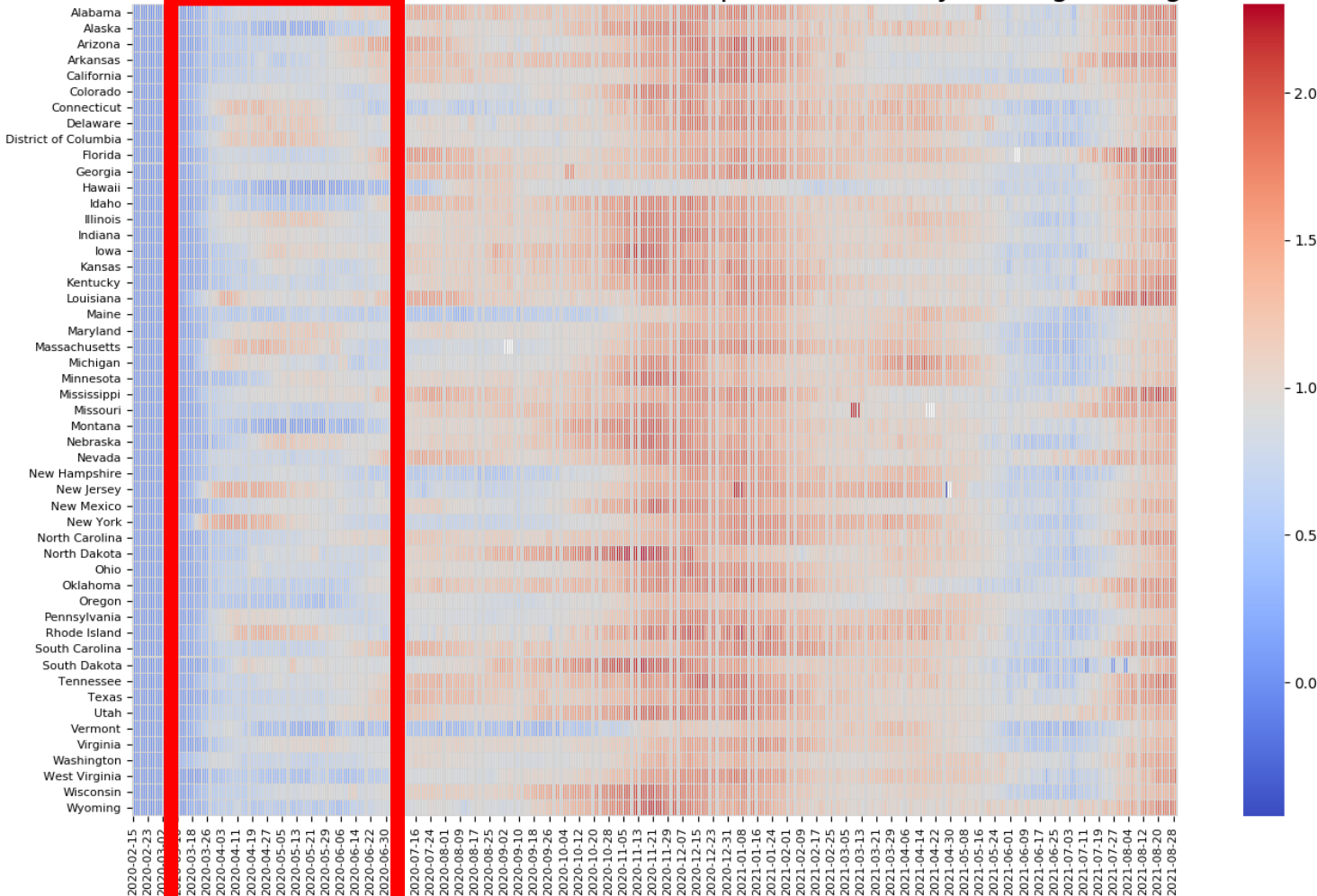
Organ Procurement Organization's (OPO) Adaptation to the COVID-19 Pandemic

CHRISTOPHER C. CURRAN, CPTC, CTBS, CTOP
SENIOR VICE PRESIDENT, ORGAN UTILIZATION
NEW ENGLAND DONOR SERVICES

Framing the Discussion

- Provide reflections on OPO experiences and approaches to dealing with COVID-19 and its impact on organ donation
 - Initial challenges faced → strategies → current status
- Common themes throughout the country's 57 OPOs
- COVID impacted OPOs differently and at different phases of the pandemic
- Forego discussion of common business practice changes seen across most industries
 - i.e., teleconference, remote work, enhanced cleaning

Daily New Covid-19 Cases Per 100k Of Population - 5 Day Moving Average



New York Times
Github Data

Visualization by:
Jason Bowling,
University of Akron

Staffing and Staff Safety

- OPO staff function in Hospital ICU and OR settings
 - Hospital Development
 - Family Services
 - Donation Coordinators
 - Organ Surgical Recovery
- Presence of OPO staff in hospitals is a crucial part of the organ donation process
- COVID transmission risk reduction strategies while maintaining OPO operations and addressing staff member concerns

Staffing and Staff Safety

▪ PPE

- Hospital shortages, expectation of OPOs to provide PPE
- PPE borrowed between OPOs
- N95 Masks: Fit testing not previously standard for OPOs
 - How to arrange fit testing?
 - Now a routine component of onboarding of clinical staff

▪ Vaccinations

- OPO staff working in clinical settings met qualifications as healthcare providers
- Challenges obtaining vaccinations
- Transplant Center or donor hospital ability to provide

OPO Onsite Hospital Presence

- Maintain the “They call, we go” philosophy for onsite response for potential organ donors
 - Perform tasks remotely when possible
 - Remote Electronic Medical Records review
 - Ongoing referral follow-up by phone
- Collaborate with hospitals on staff response plans and seek their input
- Reduce case times
- Avoid specifically designated COVID units

Hospital Development

- Hospitals sought to reduce visitor traffic
 - Perform rounding with hospital staff remotely to maintain relationships and visibility
 - Zoom video education sessions
 - Create pre-recorded donation education programs
 - Educate travelers to referral triggers, hospital donation policies and the donation process
 - Respect hospital staff circumstances (stress, overwork, loss) and look for ways to show appreciation for the work unrelated to organ donation

Hospital Resources

- Hospital capacity limited
 - Need for bed space for COVID or other critically ill patients
- Donor management challenges
 - Ventilators, ECMO and dialysis
- Staffing shortages
- Designated COVID ICUs vs. mixed units
- PPE shortages
- OR availability (staffing reassigned)

CMS Adult Elective Surgery and Procedures Recommendations:

Limit all non-essential planned surgeries and procedures, including dental, until further notice

To aggressively address COVID-19, CMS recognizes that conservation of critical resources such as ventilators and Personal Protective Equipment (PPE) is essential, as well as limiting exposure of patients and staff to the SARS-CoV-2 virus. Attached is guidance to limit non-essential adult elective

Tiers	Action	Definition	Locations	Examples
Tier 1a	Postpone surgery/procedure	Low acuity surgery/healthy patient-outpatient surgery Not life-threatening illness	HOPD* ASC** Hospital with low/no COVID-19 census	-Carpal tunnel release -EGD -Colonoscopy -Cataracts
Tier 1b	Postpone surgery/procedure	Low acuity surgery/unhealthy	HOPD ASC	-Endoscopies

Tier 3b	Do not postpone	High acuity surgery/unhealthy patient	Hospital	-Transplants -Trauma -Cardiac w/ symptoms -limb threatening vascular surgery
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- Current and projected COVID-19 cases in the facility and region.
 - Consider the following tiered approach in the table below to curtail elective surgeries. The decisions should be made in consultation with the hospital, surgeon, patient, and other public health professionals.
- Supply of PPE to the facilities in the system
- Staffing availability
- Bed availability, especially intensive care unit (ICU) beds
- Ventilator availability
- Health and age of the patient, especially given the risks of concurrent COVID-19 infection during recovery
- Urgency of the procedure.

			19 census	
Tier 3a	Do not postpone	High acuity surgery/healthy patient	Hospital	-Most cancers -Neurosurgery -Highly symptomatic patients
Tier 3b	Do not postpone	High acuity surgery/unhealthy patient	Hospital	-Transplants -Trauma -Cardiac w/ symptoms -limb threatening vascular surgery

Donor Family Interactions

- Hospitals limited family visitors
 - Face-to-face meetings for donation authorization
 - Donation conversations by phone or video conference

Donor Medical Suitability Screening

- Initially SARS-CoV-2 positivity was considered an exclusion for organ donation
- Donor Risk Assessment Questionnaire
 - Questions pertaining to travel
 - Reported exposure to others with COVID-19
- Chest CT
- SARS-CoV-2 RT-PCR testing had not been easily available
- OPOs are now recovering organs from donors who test positive for SARS-CoV-2 RT-PCR

COVID-19 Testing

- Most Infectious Disease Laboratories in use by OPOs are unable to routinely perform SARS-CoV-2 RT-PCR testing
 - Testing became available initially at few regional labs
- OPOs sought SARS-CoV-2 RT-PCR testing by affiliated hospitals and regional labs, though still some challenges
- Current OPTN Policy/AST Guidance:
 - All deceased donors should be tested for SARS-CoV-2 infection using RT-PCR from the upper respiratory tract within 72 hours, but ideally as close to organ recovery as possible
 - All potential lung donors should be tested for SARS-CoV-2 infection using RT-PCR from the lower respiratory tract

https://www.myast.org/sites/default/files/Donor%20Testing%20Document_07.07.21.pdf

Organ Allocation

- Hospital resources impacted transplant program resources
 - Acceptance practices
 - Concern for transplant recipient length of stay post transplant
- Concern for COVID transmission from donors
- Concern of travel to recover organs in areas of high COVID transmission
- Pre-Transplant COVID testing of intended candidate now standard

Organ Procurement

- Donor Special Care Units
- Limitation of visiting recovery teams
 - State travel advisories/limitations and quarantine requirements post travel
 - Hospitals and OPOs wanting to limit visitors from areas of high COVID transmission
 - Encouraged reliance on local recovery teams
- OPOs reducing travel to other service areas
 - Encouraged host OPOs to provide all perfusion services for incoming teams
- Vaccination requirements for visiting teams

Impact of COVID-19 on Transplant Centers in the United States



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Paucity of data

Early Description of Coronavirus 2019 Disease in Kidney Transplant Recipients in New York

The Columbia University Kidney Transplant Program*

Department of Medicine, Division of Nephrology, Columbia University Vagelos College of Physicians and Surgeons, New York, New York

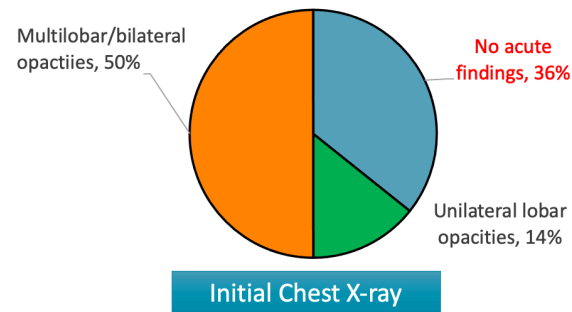
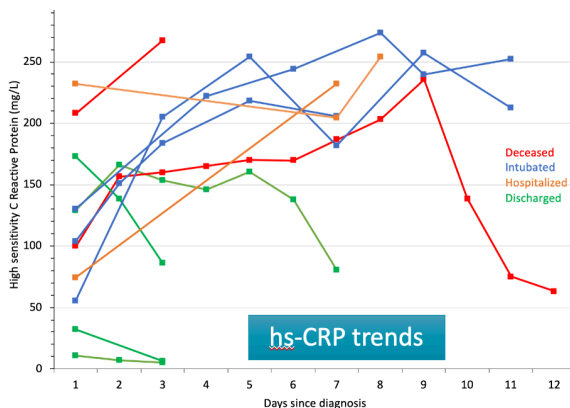
Table 1. Characteristics of kidney transplant recipients with COVID-19

Characteristics	All Patients, n=15
Baseline characteristics	
Age, yr	51 (IQR, 28–72; range, 21–78)
Female, n (%)	5 (33)
Time since transplant, mo	49 (IQR, 38–118; range, 0–232)
Deceased donor, n (%)	12 (80)
Multiorgan recipient, n (%)	2 (13)
Maintenance immunosuppression, n (%)	
Tacrolimus	14 (93)
Mycophenolate mofetil or mycophenolic acid	12 (80)
Belatacept	2 (13)
Leflunomide	1 (7)
Azathioprine	1 (7)
Prednisone	10 (67)
Clinical presentation, n (%)	
Fever	13 (87)
Cough	9 (60)
Fatigue/malaise	4 (27)
Dyspnea (exertional or rest)	4 (27)
Diarrhea	3 (20)
Myalgia	2 (13)
Hemoptysis	1 (7)
Emesis	1 (7)

Table 2. Clinical management and outcomes of kidney transplant recipients with COVID-19

Clinical Management and Outcomes	All Patients, n=15 (%)
Change in immunosuppression	
Discontinued only MMF/MPA/AZA/leflunomide	10/14 (71)
Prednisone decreased	1/10 (10)
Belatacept infusion postponed	1/2 (50)
Discontinued all immunosuppression	2 (14)
Replaced tacrolimus and MMF with prednisone	1 (7)
No change	1 (7)
Anti-COVID-19 therapies	
Hydroxychloroquine without azithromycin	4 (27)
Hydroxychloroquine plus azithromycin	9 (60)
Tocilizumab	1 (7)

Labs on Diagnosis	Median	(Range)
White blood cell count, x1000/ μ l	4.8	(2.1 - 12.7)
Absolute lymphocyte count/ μ l	800	(110 - 1410)
Ferritin, ng/mL	471	(93 - 1963)
Lactate dehydrogenase, U/L	275	(113 - 450)
Procalcitonin, ng/mL	0.46	(0.08 – 18.7)
Erythrocyte sedimentation rate, mm/hr	40.5	(0 - 75)
C-reactive protein, mg/L	104	(0.3 - 232)
Interleukin-6, pg/mL	24	(<5 - 120)



Early Outcomes for Transplant Recipients with COVID-19

Abrishami et al. [9]	12 patients	Hospitalized	Shahid Beheshti University of Medical Sciences, Tehran, Iran
Akalin et al. [10]	36 patients	Hospitalized and outpatient	Montefiore Medical Centre, Bronx, NY, USA
Alberici et al. [11]	20 patients	Hospitalized	University of Brescia, Brescia, Italy
Banerjee et al. [12]	7 patients	Hospitalized and outpatient	St. George's University Hospital, National Health Service Foundation Trust, London, UK
Fernández-Ruiz et al. [13]	8 patients	Hospitalized	Instituto de Investigación Sanitaria Hospital '12 de Octubre', Madrid, Spain
Columbia University Kidney Transplant Program [14]	15 patients	Hospitalized	Columbia University Irving Medical Centre, NY, USA
Husain et al. [15]	22 patients	Hospitalized and outpatient	Columbia University Irving Medical Centre, NY, USA
Montagud-Marrahi et al. [16]	33 patients	Hospitalized	Hospital Clinic, Barcelona, Spain
Nair et al. [17]	10 patients	Hospitalized	Northwell Health, Manhasset, NY, USA
Trujillo et al. [18]	26 patients	Hospitalized	Instituto de Investigación Sanitaria Hospital '12 de Octubre', Madrid, Spain
Zhang et al. [19]	5 patients	Hospitalized	Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China
Zhu et al. [20]	10 patients	Hospitalized	Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China

ICU Admission	34%
Mechanical ventilation	19.7%
Died	21%
Deaths among pts on ventilators	72.7%

Oltean M. et al. Inf Dis 2020



Changes in Center-Level Operations

- Increased selectivity with respect to candidates and organ utilization
- Increase utilization of telemedicine visits for all candidates to lower in person clinic volume
- Creation of specific timeslots for individuals with COVID-19 in clinic and infusion centers
- Changes in patient flow to limit risk of nosocomial infections
- Increased remote monitoring for recent recipients and recognition of infections that can be managed as outpatient

Management of Recipients with COVID-19 as Outpatients

- Careful monitoring of patients with:
 - Self-monitored temperature and, when possible, pulse oximetry
 - Regular protocolized check in by the transplant team
 - 27% needed hospitalization eventually
 - Median of 7 days - but as late as 16 days post symptom onset
 - Median time to resolution of symptoms for those not hospitalized was 12 days
- Labor intensive undertaking to closely monitor patients over the phone routinely but is associated with good outcomes for patients

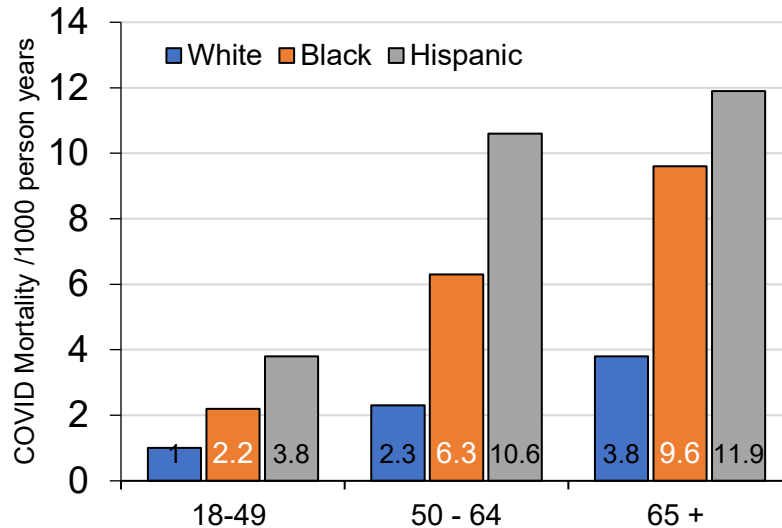
Immunosuppression Management

Asymptomatic	
No risk factors	<ul style="list-style-type: none">No change
Risk factors	<ul style="list-style-type: none">One step reduction (e.g. antimetabolite 50% reduction)
Symptomatic	
Mild symptoms	<ul style="list-style-type: none">One step reduction with close monitoringElimination of antimetabolite if high risk or symptoms persist for 3-5 days
Moderate symptoms	<p>Cessation of antimetabolite Early hospitalization for progressive symptoms for close observation Consider:</p> <ul style="list-style-type: none">Introduction of steroids @ 20mg/dayLowering of CNI trough levels based on immunological risk vs resp disease

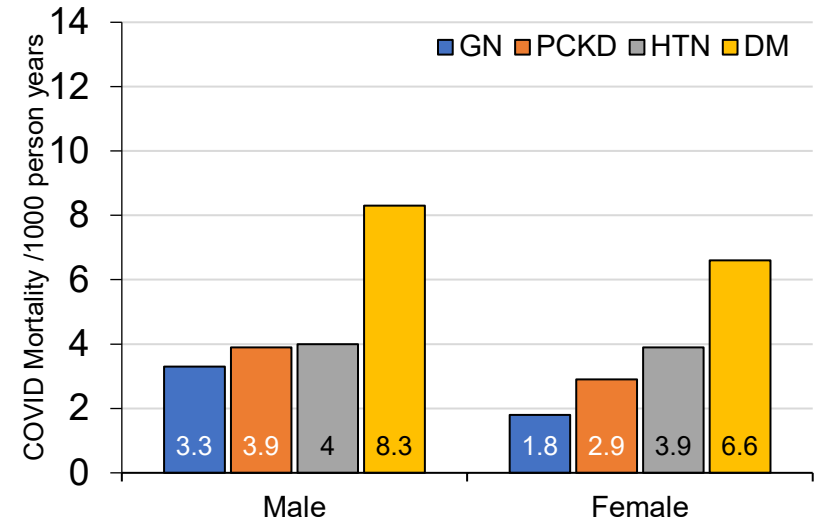
Risk factors include age > 60, BMI > 30 Kg/m², diabetes, hypertension and CKD

Higher COVID-19 Mortality Rate Among Specific Waitlist Candidate Groups

By race and age

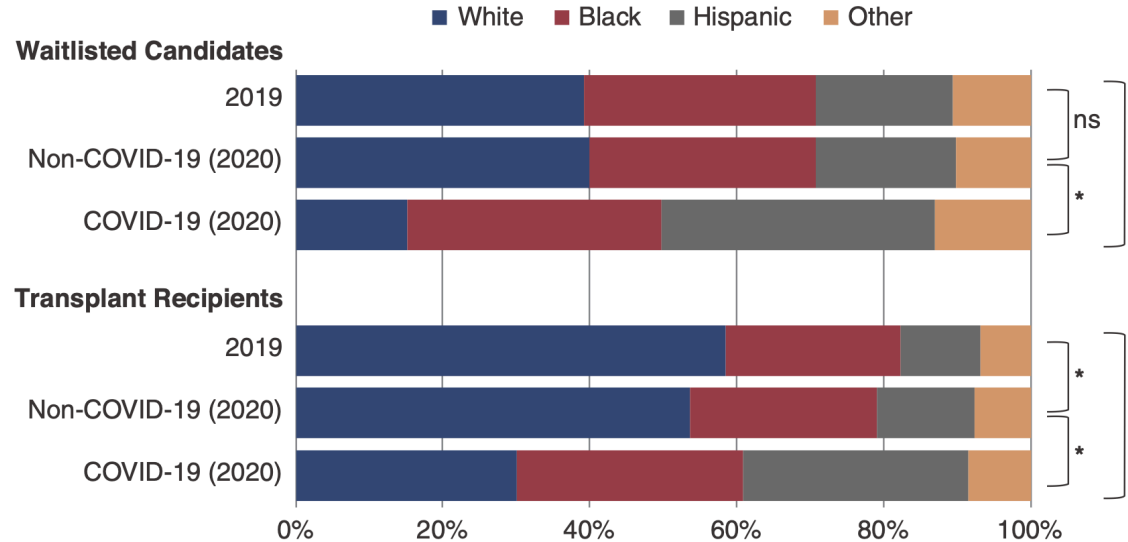


By gender and diagnosis



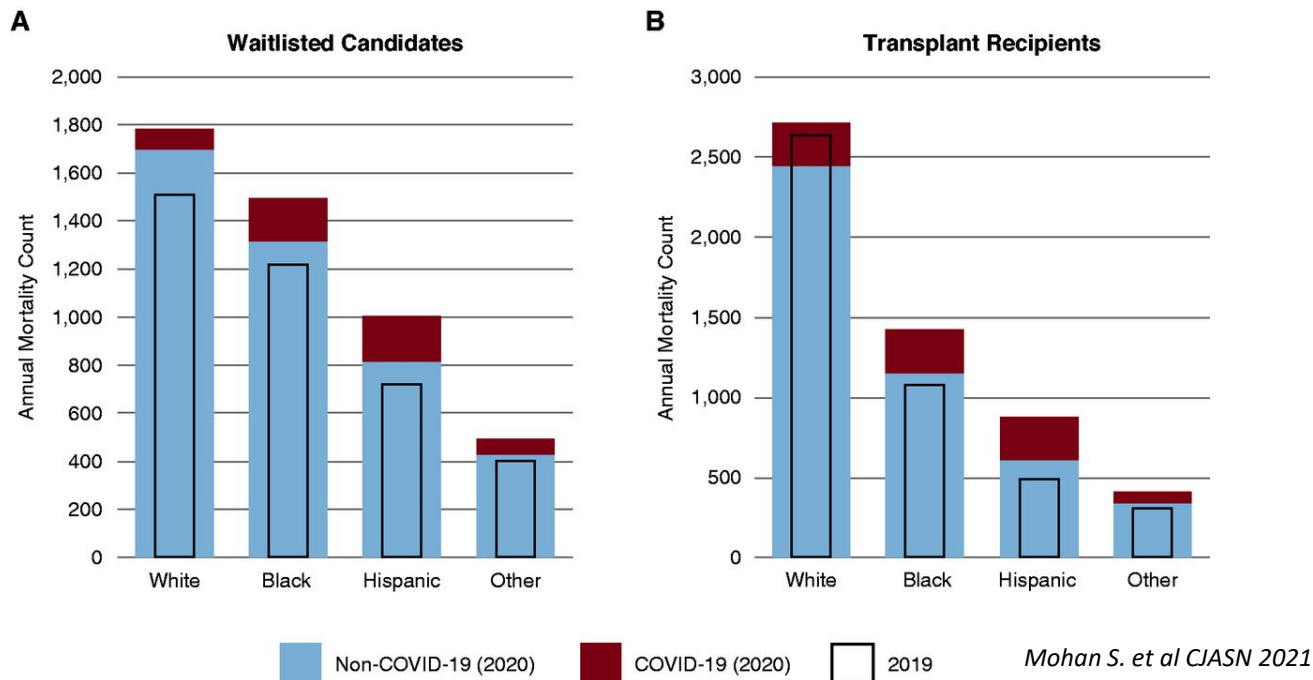
*Candidate age on March 1st, 2020 or the date of listing if after March 1st, 2020. 'Other' race/ethnic group not displayed

Distribution of Race and Ethnicity Among Deaths of Kidney Transplant Candidates and Recipients



Mohan S. et al CJASN 2021

Deaths Attributed to COVID-19



Current Considerations for Transplant Center Operations

- Telemedicine visits to lower risk of exposure and transmission have become critical
- Clinic visits and infusion visits for recipients with COVID-19 create significant logistical challenges
- Vaccination has dramatically lowered the risk of COVID related hospitalization and mortality for recipients
 - Many, if not most, centers require vaccination for transplant candidates
 - Early post transplant COVID-19 infections pose the greatest risk to recipients
 - Candidates/donors are screened for COVID-19 prior to surgery
- Improved therapeutic options have lowered the risk of adverse outcomes in the immunosuppressed patient
- Former and current living donors are not at an increased risk
 - Vaccination encouraged to lower risk of nosocomial infections and transmission during hospital stay

Contact ASPR TRACIE



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1-844-5-TRACIE



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