Challenges in Kidney Transplant in the COVID-19 Pandemic

Implications for Patients & Referring Providers
Welcome and Opening Remarks

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From the Front Lines of the COVID-19 Pandemic

Sumit Mohan, MD, MPH, FASN
Associate Professor of Medicine and Epidemiology
Columbia University Medical Center
The COVID Pandemic in New York

300,200 134,874 14,427
NYC tested NYC confirmed cases NYC probable deaths

<table>
<thead>
<tr>
<th>Age group</th>
<th>Cases</th>
<th>Hospitalized</th>
<th>%</th>
<th>Deaths</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 17</td>
<td>2,707</td>
<td>232</td>
<td>9%</td>
<td>3</td>
<td>0%</td>
</tr>
<tr>
<td>18 – 44</td>
<td>49,889</td>
<td>5,105</td>
<td>10%</td>
<td>502</td>
<td>10%</td>
</tr>
<tr>
<td>45 – 64</td>
<td>49,383</td>
<td>12,675</td>
<td>26%</td>
<td>2,783</td>
<td>22%</td>
</tr>
<tr>
<td>65 – 74</td>
<td>17,072</td>
<td>8,127</td>
<td>48%</td>
<td>3,056</td>
<td>38%</td>
</tr>
<tr>
<td>≥ 75</td>
<td>15,547</td>
<td>9,605</td>
<td>62%</td>
<td>6,146</td>
<td>64%</td>
</tr>
</tbody>
</table>

https://projects.thecity.nyc/2020_03_covid-19-tracker/
New cases and tests in NYC by day

New cases: 3,561

Cumulative confirmed cases in NYC

Cases: 138,435

Note: Current data will be incomplete until the following day and new cases may lag new tests. Testing data unavailable prior to March 17. NYC count: April 21, 6:00 PM, NYC tests: April 21, 11:59 PM
Sources: NYC Department of Health and Mental Hygiene and NYS coronavirus briefings

https://projects.thecity.nyc/2020_03_covid-19-tracker/
NYC coronavirus hospitalizations

- ICU hospitalizations
- Total hospitalizations

10,370 hospitalized

3,050 ICU

Sources: NYC Department of Health and Mental Hygiene, April 17, 6:00 PM

Capacity at permanent hospitals in NYC

All beds

- 24,037 beds
- 19,191 occupied

Sources: Gov. Andrew Cuomo’s office, April 21, 12:00 AM

ICU beds

- 4,035 beds
- 3,445 occupied

Sources: Gov. Andrew Cuomo’s office, April 21, 12:00 AM
The COVID Pandemic @ Columbia University Irving Medical Center

- March 2\textsuperscript{nd} – April 1\textsuperscript{st} admitted 1150 patients with COVID19
  - 257 (22%) were critically ill requiring ICU admission including 13 HCW
  - 221 required mechanical ventilation
  - 30\% of ICU admissions developed AKI
- At the peak – 231 prevalent ICU patients on mechanical ventilators
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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All Patients, n=15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline characteristics</td>
<td></td>
</tr>
<tr>
<td>Age, yr</td>
<td>51 (IQR, 28–72; range, 21–78)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>5 (33)</td>
</tr>
<tr>
<td>Time since transplant, mo</td>
<td>49 (IQR, 38–118; range, 0–232)</td>
</tr>
<tr>
<td>Deceased donor, n (%)</td>
<td>12 (80)</td>
</tr>
<tr>
<td>Multiorgan recipient, n (%)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Maintenance immunosuppression, n (%)</td>
<td></td>
</tr>
<tr>
<td>Tacrolimus</td>
<td>14 (93)</td>
</tr>
<tr>
<td>Mycophenolate mofetil or mycophenolic acid</td>
<td>12 (80)</td>
</tr>
<tr>
<td>Belatacept</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Prednisone</td>
<td>10 (67)</td>
</tr>
<tr>
<td>Clinical presentation, n (%)</td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>13 (87)</td>
</tr>
<tr>
<td>Cough</td>
<td>9 (60)</td>
</tr>
<tr>
<td>Fatigue/malaise</td>
<td>4 (27)</td>
</tr>
<tr>
<td>Dyspnea (exertional or rest)</td>
<td>4 (27)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Hemoptysis</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Emesis</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>
Table 2. Clinical management and outcomes of kidney transplant recipients with COVID-19

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

<table>
<thead>
<tr>
<th>Test</th>
<th>Median</th>
<th>(Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White blood cell count, x1000/μl</td>
<td>4.8</td>
<td>(2.1 - 12.7)</td>
</tr>
<tr>
<td>Absolute lymphocyte count/μl</td>
<td>800</td>
<td>(110 - 1410)</td>
</tr>
<tr>
<td>Ferritin, ng/mL</td>
<td>471</td>
<td>(93 - 1963)</td>
</tr>
<tr>
<td>Lactate dehydrogenase, U/L</td>
<td>275</td>
<td>(113 - 450)</td>
</tr>
<tr>
<td>Procalcitonin, ng/mL</td>
<td>0.46</td>
<td>(0.08 – 18.7)</td>
</tr>
<tr>
<td>Erythrocyte sedimentation rate, mm/hr</td>
<td>40.5</td>
<td>(0 - 75)</td>
</tr>
<tr>
<td>C-reactive protein, mg/L</td>
<td>104</td>
<td>(0.3 - 232)</td>
</tr>
<tr>
<td>Interleukin-6, pg/mL</td>
<td>24</td>
<td>(&lt;5 - 120)</td>
</tr>
</tbody>
</table>

### hs-CRP trends

- Deceased
- Intubated
- Hospitalized
- Discharged

### Initial Chest X-ray

- No acute findings, 36%
- Unilateral lobar opacities, 14%
- Multilobar/bilateral opacities, 50%
### Outcomes

**AKI**  
- Intubation required: 4 (27)  
- Days between admission and intubation ($n=4$): 5 (range, 0–9)

**Hospitalization disposition**
- Died: 1 (7)  
- Discharged: 8 (53)  
- Days between admission and discharge ($n=8$): 4.5 (range, 0–9)

**Hospitalization ongoing**
- Days between admission and end of follow-up ($n=6$): 7 (range, 3–11)
Managing recipients as outpatients

• Initial 41 patients managed as outpatients
  • Self monitored temperature, regular check ins and if possible – pulse oximetry
  • 27% needed hospitalization eventually
    • usually at a median of 7 days after symptom onset but as late as 16 days after
    • Exertional dyspnea was a predictor of eventual need for hospitalization
• Currently > 35 phone calls per day to check in with patients
<table>
<thead>
<tr>
<th></th>
<th>Outpatient only</th>
<th>Hospitalized</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%) or median (IQR)</td>
<td>n=30 (73)</td>
<td>n=11 (27)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>21 (70)</td>
<td>9 (82)</td>
<td>0.45</td>
</tr>
<tr>
<td>Age, years</td>
<td>48 (41-63)</td>
<td>56 (41-64)</td>
<td>0.72</td>
</tr>
<tr>
<td>Time since transplant, months</td>
<td>41 (17-63)</td>
<td>43 (17 - 102)</td>
<td>0.53</td>
</tr>
<tr>
<td>Deceased donor</td>
<td>15 (57)</td>
<td>6 (55)</td>
<td>0.90</td>
</tr>
<tr>
<td>Hypertension</td>
<td>27 (90)</td>
<td>10 (91)</td>
<td>0.93</td>
</tr>
<tr>
<td>Diabetes</td>
<td>7 (23)</td>
<td>4 (36)</td>
<td>0.40</td>
</tr>
<tr>
<td>Body mass index, kg/m2</td>
<td>26.8 (25.1-32.1)</td>
<td>26.5 (25.8-32.0)</td>
<td>0.89</td>
</tr>
<tr>
<td>Baseline serum creatinine (md/dL)*</td>
<td>1.4 (1.1-1.9)</td>
<td>1.8 (1.4- 2.9)</td>
<td>0.10</td>
</tr>
</tbody>
</table>

**Maintenance Immunosuppression**

<table>
<thead>
<tr>
<th></th>
<th>Outpatient only</th>
<th>Hospitalized</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcineurin inhibitor</td>
<td>23 (77)</td>
<td>8 (73)</td>
<td>0.8</td>
</tr>
<tr>
<td>Mycophenolate mofetil/mycophenolate sodium</td>
<td>25 (83)</td>
<td>6 (55)</td>
<td>0.06</td>
</tr>
<tr>
<td>Prednisone</td>
<td>11 (37)</td>
<td>5 (45)</td>
<td>0.61</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>4 (13)</td>
<td>1 (9)</td>
<td>0.71</td>
</tr>
<tr>
<td>Belatacept</td>
<td>7 (23)</td>
<td>2 (18)</td>
<td>0.72</td>
</tr>
</tbody>
</table>

**Symptoms**

<table>
<thead>
<tr>
<th></th>
<th>Outpatient only</th>
<th>Hospitalized</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>23 (77)</td>
<td>10 (91)</td>
<td>0.31</td>
</tr>
<tr>
<td>Cough</td>
<td>18 (60)</td>
<td>5 (45)</td>
<td>0.41</td>
</tr>
<tr>
<td>Dyspnea (exertional or rest)</td>
<td>7 (23)</td>
<td>9 (82)</td>
<td>0.001</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>7 (2)</td>
<td>4 (36)</td>
<td>0.40</td>
</tr>
<tr>
<td>Myalgia/arthritis</td>
<td>10 (33)</td>
<td>1 (9)</td>
<td>0.12</td>
</tr>
<tr>
<td>Fatigue/malaise</td>
<td>6 (20)</td>
<td>4 (46)</td>
<td>0.28</td>
</tr>
<tr>
<td>Seen in clinic for evaluation</td>
<td>4 (13)</td>
<td>4 (36)</td>
<td>0.10</td>
</tr>
</tbody>
</table>
Summary

• Clinical presentation similar to that of the general population
• Initial Chest X-rays can be normal
• Optimal immunosuppression management strategy yet to be defined. Most common step is reduction of the anti-metabolite
• Less severe cases can be managed as outpatient when coupled with careful monitoring
  • Worsening dyspnea associated with need for hospitalization
Challenges in Transplant Program Operations in the COVID-19 Pandemic: 
Implications for Patients & Referring Providers

Roslyn B. Mannon, MD, FASN
Professor of Medicine, Pathology and Microbiology
University of Nebraska Medical Center
How have transplant programs responded to the pandemic?

Transplantation is a CMS designated Tier 3B surgical procedure (akin to trauma, vascular procedures)

- Kidney transplant programs continue to function, albeit with restrictions.
- Programs have had to accommodate changes to their facilities and staff, deployed to COVID specific tasks, and adjustments to OR time and ICU beds.
- Patient flow into transplant centers has been reduced significantly.
- Organ procurement organizations (OPOs) have had substantial adjustments to their operations.

1Boyarsky et al. Am Jnl Transplant 2020, in press
• 72% have stopped living donor transplantation; 25% have modified their current practices²
  – Transplantation in pre-emptive “healthy” patients with CKD or in those lacking dialysis access
  – Evaluation and education via telehealth with multidisciplinary team members
  – Labs via home visits or local labs, readying potential living donor for in center imaging / transplant surgery

¹United Network of Organ Sharing unos.org/covid accessed 04/19/2020
²Boyarsky et al. Am Jnl Transplant 2020, in press
80% of programs have modified their deceased donor kidney programs\textsuperscript{2,3,4}

- No pre-emptive transplants versus pre-emptive transplants in patients with few co-morbidities
- Use of high quality organs
- Very highly sensitized recipients
- Dialysis patients with limited co-morbidities
Challenges to Deceased Donation and OPO Operations

- Decline in traumatic deaths nationally
- Dramatic rise in hospital and ICU admissions for COVID19 patients limiting possibilities for donation¹
  - LiveOn New York OPO: “of ~600 calls about deaths to the OPO March 30, only 7 eligible donor “cases” (down from the typical 35 donor cases/day)”
- Consenting organ donation in current pandemic
  - Association of Organ Procurement Organization (AOPO) policies in terms of physical contact
  - Challenges to connect with donor families in ICUs with physical separation pending testing
- Challenges with test availability and inconsistent access to testing methods
  - As of April 13, 2020, no donor transmission
  - Donors deferred if they are SARS-COV2 positive or if symptomatic with suspected infection pending testing

Challenges of Deceased Donation Transplantation

**• Changes in wait list management**
  - Many centers with significant number of wait list inactivations for COVID19 concerns (3/17/2020)
  - UNOS approved emergency policy package that included wait time modification for pre-emptive registrations (04/03/2020)

**• Challenges in organ placement/allocation**
  - Allocation rules are still in place
  - Local recovery teams preferred
  - Issues with OR and ICU time, and staff availability

**• Patients declining organ offers**
  - Concerns to come into the hospital
  - Concerns for the possibility that the donor could be positive (false negative testing)

---

United Network of Organ Sharing unos.org/covid accessed 04/19/2020
Https: www.aopo.org/information-about-covid-19 accessed 04/19/2020
Challenge and change in deceased donor organ transplantation

Perception of Anticipated and Current Resource Shortages as of 03/24/2020

- Telehealth implementation by the vast majority of transplant centers
  - Convenient and multidisciplinary
  - In home / at home lab testing
- Required imaging and other testing (cardiac echo, stress test) including physical exams pending...
- Utilizing virtual platforms that are HIPPA compliant to proceed with multidisciplinary listing decisions

1Boyarsky et al. Am Jnl Transplant 2020, in press
Patient Management: Post-transplant Care

• Post transplant clinic visits
  – Limiting health care in outpatient hospital clinics (@transplant centers)\(^1\)
  – 98% of surveyed have converted to telephone health or video chat session with new CMS guidance for telehealth (March 17, 2020).

• Post transplant lab monitoring
  – Home health visits for lab testing when possible
  – Strategies include hospital network services, and utilizing post-transplant monitoring test companies to include standard labs
  – Extending some of the monitoring periods (eg. twice a week to weekly; 21% of surveyed programs)\(^1\)

\(^1\)Boyarsky et al. Am Jnl Transplant 2020, in press
When things go back to normal....

• When will things go back to “normal”?  
  – Some areas are on downswing but COVID19 very prevalent and some areas are on the upswing  
  – Much like the economy, there will be a gradual reopening of transplant programs to full capabilities

• Reliance on diagnostic PCR and antibody detection
• Will telehealth and home labs become the new normal?
• Not clear of second phase or upswing that may occur
• How will programs handle the “glut” of new evaluations / living donors / cases?
Useful Webpages and References

• [https://unos.org/covid/](https://unos.org/covid/)
SARS-CoV-2 Clinical Perspectives
Kidney Transplantation

Nicolae Leca, MD, FASN
Medical Director, Kidney and Pancreas Transplantation
University of Washington Medical Center

“It was the best of times,
It was the worst of times
It was the spring of hope,
It was the winter of despair”

Charles Dickens
Transplantation - Process Adaptations

- Clinic Visits – Telehealth
- Blood draws – Home services
- Medications – Extended supplies
- Pre-Transplant workup – Policy modifications
University of Washington COVID19 Registry Update

- 151 kidney transplant recipients with COVID19 infection - median age 56
  - Median 5 years post tx, 6 transplanted in 2020, max 30 years
- Presentation: 80% cough, 57% fever, 37% diarrhea
- 74% hospitalized, 31% in ICU (25% intubated)
- 67% treated with some experimental therapy
- 83% had immunosuppression reduced (elimination of antimetabolite)
- 37% graft dysfunction, 9% RRT
- 12% deceased
- 37 re-tested, several with alternating results, 3 still positive at 3 weeks
University of Washington
Multi-Site Case Report Registry Project

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https://drive.google.com/drive/folders/1JDtVagiFKly9AHjJmYpgVjO2CzoQzoa1?usp=sharing
Diagnostic Testing

- Nasopharyngeal swabs → RT-PCR (multiple platforms)
- Unclear sensitivity/specificity/accuracy (of sampling)/validity
- Clinical negativity: 14 days after symptom onset and 3 days after symptom resolution
- Is testing required to ensure negativity?
  - Yes for inpatients (UW guideline) x2 in 24hrs
- Serologic tests: what are the implications of antibodies?
Immunosuppression Management

- Complete discontinuation of immunosuppression is not generally warranted
  - ‘Sweet spot’ of immunosuppressive strength?

- Discontinuation of anti-metabolite

- Substantial decrease in CNI target levels

- Steroid pulsing not routinely indicated
Therapeutic Options

➢ There are no FDA-approved or clinically proven therapies

➢ Interventions are available. Not evidence-based/not implicit effective
  ▪ In vitro anti-viral activity agents
  ▪ Have been used against MERS/SARS
  ▪ Target pathophysiology of severe acute respiratory syndrome

➢ Clinical trials are preferred
  ▪ Not indicated for outpatients
  ▪ PEP not indicated* (HCW, home contacts)

➢ Supportive care is the mainstay of treatment for patients with COVID-19
COVID-19 KIDNEY TRANSPLANTATION

Hydroxychloroquine/Chloroquine

- Established in vitro anti-viral mechanism of action
- FDA Emergency use activation for COVID19 – approval not implied
- Toxicity: QT prolongation; additive seizure risk with CNI
- HCQ/Azithromycin not rigorously studied – may increase cardiac toxicity
2. Hydroxychloroquine plus Azithromycin in 80 COVID-19 Patients with >6 Day Follow up: 81% discharged, 1 death, 83% pcr negative

3. Retrospective Analysis of Hydroxychloroquine in 84 Hospitalized Patients with COVID-19: no differences in death, transfer to ICU or ARDS rates (97 controls). 10% EKG changes

• Source: Gautret P, et al. Travel Med Infect Dis. 2020:101663
**Remdesivir**

- Broad-spectrum action against RNA-viruses
- FDA status: Investigational
- Administration IV 200mg day 1, 100mg daily (10d)
- Toxicity: GI, elevation LFTs (typically 2-3 fold)
  - eGFR<30ml/min excluded from studies

*Activity Against SARS-CoV-2 (2019-CoV): Vero E6 Cells*)

- **EC$_{50}$=0.7 µM**
- **Cytotoxicity CC >100**

Conclusions: “In this cohort of patients hospitalized for severe Covid-19 who were treated with compassionate-use remdesivir, clinical improvement was observed in 36 of 53 patients (68%)
Anti-IL6 Receptor Blocker - Tocilizumab

- **Rationale for use:**
  - Elevated levels of inflammatory cytokines (as seen in Covid19) are associated with increased risk of ARDS and death.
  - Effective in treating cytokine storm in CAR-T therapy

- **FDA approved for:** cytokine release syndrome, RA.

- **Toxicity:** Injection site reactions, LFT abnormalities

- **Evidence:** uncontrolled cohorts, consistent improvement in inflammatory markers
COVID-19 KIDNEY TRANSPLANTATION

Therapies Not Recommended

- Lopinavir/Ritonavir (Kaletra) – evidence based
- Ribavirin +/- Interferon (alfa-2a/b, beta-1)
- Ivermectin
- Corticosteroids
- NSAIDS
- IVIg
- ACEI/ARB*
COVID-19 Treatment

Our main goal is to provide up-to-date information and teaching slide decks focused on clinical trials and published data related to potential high-impact treatments of persons with COVID-19.

U.S. Clinical Trials
Quick links to COVID-19 clinical trials and expanded access programs in the United States. The treatment regimens and trial list are organized alphabetically.

Treatments
Selected high-impact and high interest COVID-19 treatments. Includes medication summaries, studies, and treatment-specific references.

Teaching Resources
COVID-19 treatment PowerPoint slide decks. All slide decks can be downloaded and used for educational purposes without obtaining permission from our website.

About this website
This website was developed at the University of Washington and is produced by the University of Washington Infectious Diseases Education and Assessment (IDEA) Program.

Editors
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University of Washington

Gretchen Snoeyenbos Newman, MD
Senior Fellow
Division of Infectious Diseases
University of Washington

https://covid.idea.medicine.uw.edu
Welcome to the UW Medicine COVID-19 Public Site. The clinical and administrative teams throughout our system (Harborview Medical Center, UW Medical Center-Montlake, UW Medical Center-Northwest, Valley Medical Center, UW Neighborhood Clinics and Airlift Northwest) and partners Seattle Cancer Care Alliance have developed policies and protocols in response to the outbreak in Western Washington. Most of these documents have been written since Monday, February 24th 2020 and are undergoing frequent revisions as the COVID-19 situation evolves. When using the documents, we caution you to be mindful of the date the document was produced and to check that against current knowledge and evolving clinical standards.

Since the outbreak began, our colleagues, locally and nationally, have been reaching out to us for assistance as they start to see cases. We hope that by sharing our work, we can assist your teams and facilities to move more quickly and to spend more time responding and less time typing.

https://covid-19.uwmedicine.org
Transplant Advocacy & Policy Updates

Krista Lentine, MD, PhD, FASN
Medical Director of Living Donation
Co-Director of Clinical Research
Mid-America Transplant/Jane A. Beckman Endowed Chair in Transplantation
Saint Louis University
Advocacy & Policy Updates

Processes of Care Impacted by COVID-19 Public Health Emergency

- Candidate Evaluation & Intake
- Deceased Donor Organ Procurement & Placement
- Transplant Procedure & Early Aftercare
- Management of the Prevalent Transplant Recipient

Foci for Advocacy

- Regulation
- Reimbursement
- Access to Care
- Patient & Provider Safety
- Research & Innovation

Stakeholders

- Patients
- Referring Providers
- Transplant Centers
- OPOs
- Regulators
- Payors
- Funding Agencies
<table>
<thead>
<tr>
<th>Domain</th>
<th>Specific Issue</th>
<th>Current Status/Comments</th>
</tr>
</thead>
</table>
| Access to Transplant Procedures| Transplant as an “Essential Procedure”              | • CMS designated Transplant as Tier 3b Surgery – do not postpone if possible (3/18/20)  
  • Feasibility depends on local safety & resource considerations |
| Candidate Allocation Priority  | Avoid Waiting Time Penalties due to Testing Barriers| • UNOS modified waiting time initiation for non-dialysis candidates (4/3/20)  
  • Programs can apply for retroactive waiting time modification for candidates with qualifying GFR they planned to register, but were unable to obtain other testing required for registration |
| Patient Safety                 | Temporary Candidate Inactivation                    | • UNOS allowed temporary inactivation of candidates for the reason of “COVID-19 Precaution” – no loss of waiting time |

https://www.cms.gov/ – March 18, 2020
https://optn.transplant.hrsa.gov/governance/policy-notices/
<table>
<thead>
<tr>
<th>Domain</th>
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| Access to Evaluation and Follow-up Care | Expand access to care via telehealth (ASN letter to Secretary, 3/19/20) | • Permit telephone interactions when two-way video technology is not available (and count towards reimbursement)  
• Include codes for transplant candidate & living donor assessments in Medicare-approved telehealth services  
• Encourage temporary allowance of care across state-lines |
| Patient Safety | Add COVID-19 testing to organ offer data system | • UNOS added COVID-19 to deceased donor infectious disease testing information in DonorNet® (4/3/20)  
• Allows accepting centers to see if testing was performed & results |
| Patient Safety | Access to COVID-19 testing | • Request prioritization of organ donors & transplant recipients (ASN letter to Secretary, 3/19/20) |

https://www.asn-online.org/policy/ – March 19, 2020
## Advocacy & Policy Updates

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<tr>
<td>Post-transplant Care</td>
<td>Access to Immunosuppression Medications</td>
<td>• Request <strong>insurers cover 90-day supplies</strong> and mail-order delivery of prescription drugs for transplant, diabetic, and ESKD patients (Memo to HHS leadership, 4/13/20)</td>
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<td>Post-transplant / Post-donation Monitoring</td>
<td>Access to Home-based Lab Sample Collection</td>
<td>• Request CMS clarify temporary qualification of transplant recipients &amp; living organ donors as homebound beneficiaries eligible for venipuncture (Memo to HHS, 4/13/20)</td>
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| Data Submission               | Relax Post-transplant / Post-donation Data Reporting | • UNOS suspended **data collection & submission requirements** for: living donor follow-up, recipient follow-up & recipient malignancy forms (backdated 3/13/20, to 9/30/20)  
  • Extend time for death or graft loss reporting  
    • **Reduce patient exposure** to COVID-19  
    • **Reduce administrative burden on centers** |

https://optn.transplant.hrsa.gov/governance/policy-notices/
## Advocacy & Policy Updates

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| Performance Metrics     | Account for impact of COVID-19 on expected donation rates, transplant rates & outcomes | • Deviations from OPTN requirements will be evaluated in the context of the national crisis  
• UNOS Membership & Professional Standards (MPSC) will look for a commitment to patient safety & stewardship of donated organs  
• MPSC & SRTR considering metrics reporting |
Advocacy & Policy: Engagement & Resources

Virtual Hill Day
April 1, 2020

TAKE ACTION ON COVID-19

ASN Podcasts
• COVID-19 Practice & Policy Updates

Staff & Leadership
• ASN Policy Staff
  • Rachel Meyer, David White, Zach Kribs, Ryan Murray, Killian Gause
• ASN Policy Committee
  • Chair: Michelle Josephson
• ASN Quality Committee
  • Chair: Scott Bieber

ASN Resources
• https://www.asn-online.org/covid-19/
  • CMS Updates
  • CDC Info
  • ASN Resources
  • Publications

Other Resources
• https://unos.org/covid/

Collaborative Partnerships

https://www.asn-online.org/policy/contact.aspx
Questions

Darlene Rodgers, BSN, RN, CNN, CPHQ
Nurse Consultant
American Society of Nephrology (ASN)
Closing Remarks

Michelle A. Josephson, MD, FASN
Professor of Medicine, Medical Director Kidney Transplant
University of Chicago Medicine
• Transplant patients with COVID-19 manifest a wide spectrum of disease severity
  • Our understanding of how best to manage immunosuppression in those who are severely ill is evolving

• Immunosuppression should not be stopped in transplant patients who are not infected

• Many transplant programs have modified activity
  • Temporarily postponing living donor transplantation and performing deceased kidney transplants on a case by case basis

• ASN and other organizations are tirelessly advocating for patients
  • Telehealth, home blood draws, guaranteed medication access, prioritized COVID-19 testing access, and making the case that transplantation surgery is not elective are some examples