Title: Operational Challenges in the COVID Era: Asymptomatic Infections and Vaccination Timing

Running title: Kidney Transplant and COVID-19

Authors: David A. Axelrod[1*], Dilek Ince[1*], Meera N. Harhay[2], Roslyn B. Mannon[3], Tarek Alhamad[4], Matthew Cooper[5], Michelle A. Josephson[6], Yasar Caliskan[7], Asif Sharfuddin[8], Vineeta Kumar[9], Alexis Guenette[7], Mark A. Schnitzler[7], Sruthi Ainapurapu[7], Krista L. Lentine[7]

1 University of Iowa / Transplant Institute, Iowa City, IA

2 Drexel University Tower Health Transplant Institute, Philadelphia, PA

3 University of Nebraska, Omaha, NB

4 Washington University, St. Louis, MO

5 Medstar Georgetown Transplant Institute, Washington, DC

6 University of Chicago, Chicago, IL

7 Saint Louis University Center for Abdominal Transplantation, St. Louis, MO

8 Indiana University, Indianapolis, IN

9 University of Alabama at Birmingham, Birmingham, AL

*Co first authors

Correspondence: David A. Axelrod, MD, MBA. Department of Surgery. University of Iowa. 200 Hawkins Dr. Iowa City, IA 52252. Telephone: 319-467-5303. Email: David-axelrod@uiowa.edu | or Krista Lentine, MD, PhD, 1201 S. Grand Blvd St. Louis, MO 63104. Email: krista.entine@health.slu.edu

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ABBREVIATIONS

AKI, acute kidney injury; COVID-19, Coronavirus Disease 2019; ICU, intensive care units; KPD, kidney paired donation; LDKT, living donor kidney transplantation; MERS-CoV, Middle East Respiratory Syndrome *Coronavirus*; PCR, polymerase chain reaction; PPE, personal protective equipment; SARS-CoV, Severe Acute Respiratory Syndrome *Coronavirus*; *U.S.,* United States.

ABSTRACT PAGE:

DA Axelrod, D Ince, MN Harhay, RB Mannon, T Alhamad, M Cooper, MA Josephson, Y Caliskan, A Sharfuddin, V Kumar, A Guenette, MA Schnitzler, S Ainapurapu, KL Lentine**.** Operational Challenges in the COVID Era: Asymptomatic infections and Vaccination Timing. Clin Transpl.

ABSTRACT

The coronavirus disease 2019 (COVID-19) pandemic has created unprecedented challenges for solid organ transplant programs. While transplant activity has largely recovered, appropriate management of deceased donor candidates who are asymptomatic but have positive nucleic acid test (NAT) for COVID-19 is unclear as this may reflect active infection or prolonged viral shedding. Furthermore, candidates who are unvaccinated or partially vaccinated continue to receive donor offers. In the absence of prospective data, transplant professionals at U.S. adult kidney transplant centers were surveyed to determine community practice (N: 92 centers, capturing 40.8% of centers and 56.6% of transplants performed). The majority (96.8%) of responding centers declined organs

for asymptomatic NAT+ patients without documented prior infection. However, 31.6% of centers proceeded with kidney transplant in NAT+ patients who were at least 30 days from initial diagnosis with negative chest imaging. Less than 7% of programs reported inactivating patients who were unvaccinated or partially vaccinated. In conclusion, despite national recommendations to wait for negative testing, many centers are proceeding with transplant in patients with positive tests due to presumed viral shedding. Furthermore, very few centers are requiring COVID-19 vaccination prior to transplantation despite early evidence suggesting reduced immunogenicity in transplant patients on immunosuppression.

Key Words

COVID-19; Kidney Transplantation; Offer acceptance; Pandemic; Practices; Waitlist management; Vaccination

Corresponding Author:

David A. Axelrod, MD. University of Iowa. Solid Organ Transplant Center. 200 Hawkins Dr. Iowa City, IA 52242. david-axelrod@uiowa.edu

INTRODUCTION

The coronavirus disease 2019 (COVID-19) has substantially impacted organ donation, transplantation, and the management of the post-transplant patient population. Two meta-analysis have shown higher hospitalization rates and intensive care and hospital mortality rates due to COVID-19 in solid organ transplant recipients when compared to the general population.[1,2] The COVID-19 pandemic initially led to a rapid decline in deceased organ donation and near cessation of living donor transplantation out of caution.[3,4] Importantly, in addition, increased waitlist mortality rates in kidney transplant candidates were observed at the onset of the national emergency period of COVID-19. When compared with transplant recipients with similar demographics and comorbidities who developed COVID-19, waitlisted patients who developed COVID-19 were more likely to require hospitalization.[5,6]

To help guide the community during the pandemic, American Society of Transplantation (AST) has developed recommendations on how and when to test deceased and living donors for SARS-CoV-2, as well as transplant practices during the pandemic.[7,8] Serum antibody testing has not been

recommended given variability in specificity based on prevalence of SARS-CoV-2 in the region. With these recommendations, solid organ transplantation has recovered to almost pre-COVID-19 levels and the total number of transplants was only slightly decreased in 2020.[4,9] COVID-19 vaccines currently available in the United States under Emergency Use Authorization confer significant protection (66%-95%) against COVID-19 in persons 16 years of age and older based on studies carried out in mostly immunocompetent hosts.[10,11] In the absence of data on efficacy and safety in solid organ transplant recipients, but based on prior knowledge on other vaccines, AST has made recommendations on safety and pre- and post-transplant timing of COVID-19 vaccinations.[12]

Despite available guidance, transplantation in the COVID-19 era is complex with areas of ongoing uncertainty. Prolonged, asymptomatic shedding of viral RNA for up to 90 days has been reported, leading to uncertainties in candidate management. The decision to transplant patients with asymptomatic SARS-CoV-2 nucleic acid testing (NAT) positivity has been evolving, with some centers requiring one to two negative NAT results prior to transplantation and others transplanting more quickly. Similarly, management of waitlist candidates who are not yet transplanted is unclear. While pre-transplant vaccination is optimal, it is not clear how centers should treat candidates who are not fully vaccinated but remain active on the deceased donor transplant list. To better elucidate these issues and current practice patterns, we designed and administered an electronic survey. Herein we report the findings based on responses at U.S. adult kidney transplant programs from 2/13/2021 to 4/29/2021.

MATERIAL AND METHODS

Survey design

The survey instrument was developed by the study investigators. The final survey instrument comprised of 10 questions addressing the management of kidney transplant candidates with asymptomatic COVID-19 infection who receive an organ offer as well as deceased donor transplant candidates who are not yet vaccinated (SDC, Table 1). The survey also queried information on the participant role (nephrologist, transplant surgeon, clinical coordinator, social worker, administrator, or other) at the transplant center. This study was approved by the Saint Louis University Institutional Review Board. The survey was also approved by the AST Education Committee and the American Society of Transplant Surgeons (ASTS).

Survey Administration

The target population was transplant program staff at U.S. adult kidney transplant programs, including surgeons, nephrologists, administrators, coordinators and social workers. Potential participants from U.S. kidney transplant programs were derived from the working group's professional connections as well as an ASTS email list provided for survey use after approval. The survey was distributed and data collected through Qualtrics Survey Software. Opportunity for self-elected participation through a Qualtrics link was also posted to professional society list servs (e.g. American Society of Transplantation (AST) Kidney Pancreas Community of Practice (COP), Infectious Disease COP, and AST Outstanding Questions in Transplantation (OQiT)), and the American Society of Transplant Surgeons (ASTS) email list. COP postings were approved by COP leadership, and the OQiT posting was approved by the AST Education Committee, and email to ASTS members was approved by the council. The first page of the survey notes that the decision to proceed indicates consent to participate. Up to two reminders were provided for non-respondents.

Statistical Analysis

Each program was represented only once in the analysis. For programs with multiple respondents, we selected a single participant to represent the program using a hierarchical algorithm. First, we prioritized responses with the most complete information (i.e., least unanswered items). Next, we prioritized surveys submitted by surgeons or nephrologists, over those from coordinators, social workers, administrators, or others. Lastly, we prioritized the earliest submitted questionnaire.

Responses to each survey question were described with percentages and frequencies. To obtain rates, we divided the number of program responses by the total number of programs who responded to the question, such that percentages reflect proportions of respondents, as per previous methods.[13-15] For questions where participants were asked to "select all that apply," the denominator for calculating percentages was the number of participants responding to that question. All analyses were performed using R for windows version 1.2.5042 (RStudio Inc., Boston, MA).

RESULTS

Survey Participants

This report describes responses from 92 unique kidney transplant centers in the United States (**SDC, Figure 1**). Respondents represented 40.8% of U.S. adult kidney transplant programs and 56.6% of volume in the year before the survey. Respondents were most commonly nephrologists (42.4%) and surgeons (40.2%), while 17.4% were other transplant professionals (**Table 1**).

Management of Patients with Asymptomatic COVID-19

Management of candidates called in for transplant who have no clinical evidence of documented COVID-19 infection but were found to have a positive test with a nasopharyngeal swab differed across programs (**Figure 1**). The majority of programs declined the organ and delayed transplantation. The length of delay varied, with 69.6% of centers requiring delay until the candidate tests negative and 27.2% delaying for a fixed period of at least 30 days without retesting. In 4.3% of centers, patients with reassuring adjunctive testing including CT scans or antibody tests were assumed to have a resolved infection and proceed with transplant.

Among candidates with documented COVID-19 infection more than 30 days prior to admission who have persistently positive testing, practices were more varied. The majority (55.4%) of centers continued to decline the organ and wait for negative testing. However, 31.6% of centers proceeded with transplant, either with negative pulmonary imagining (19.6%) or positive pre-transplant antibody testing (12.0%). Other, unspecified protocols, were followed in 23.9% of centers to allow transplantation.

COVID-19 Vaccination and Waitlist Management

Nearly all centers (93.5%) currently encourage vaccination for all candidates on the waiting list and prior to living donation (**Table 2**). Only one center reported that they have decided to inactivate unsensitized candidates (cPRA<80%) until they are vaccinated, and five centers report inactivating candidates who have received their first vaccine dose pending receipt of their second dose. The majority of centers (83.7%) continue to accept organs for unvaccinated patients, and delay vaccination for 4-12 weeks after transplantation. Similarly, 51.1% report accepting organs for candidates with a single vaccine dose and delaying vaccination with the second dose for 4-12 weeks after transplantation. For high sensitized patients, no centers report inactivating all unvaccinated patients and six centers were inactivating patients who received their first dose until they received their second dose. Again, most centers reported not delaying transplant for unvaccinated (80.4%) or partially vaccinated (56.5%) candidates.

Tracking and coordination of vaccination varied widely across centers (**Table 3**). Programs reported that ascertaining vaccination status at the primarily at the time of offer in 64.8% of cases. While 62.6% of centers request patients to update the center on their vaccination status, only 23.1% have a process for direct patient inquiries. For unvaccinated recipients of a deceased donor transplant, the recommendations for delaying vaccination after transplantation varied with 42.4% of centers recommending >4-8 weeks and 54.3% recommending > 8 weeks. For unvaccinated candidates who have living donors, recommendations on the duration to wait for transplant after completion of vaccination varied widely (0-2 weeks: 12.0%, >2-4 weeks: 53.3%, >4-8 weeks: 29.3%, and >8 weeks: 4.3%).

DISCUSSION

The COVID-19 pandemic has significantly changed healthcare delivery across the world,[16-18] including profound impacts on organ transplantation.[19-22] Management of waitlist patients who present for transplant without symptoms but with a positive COVID nasopharyngeal swab pose a significant challenge as many of these patients may have a resolving infection. Currently, in the absence of documented infection, the majority of centers are declining to transplant candidates until either they have negative tests or a pre-defined period has passed. For candidates presenting for transplant with a history of documented COVID-19 infection, approximately one third of centers will proceed even with a positive test, if imaging is clear. With regard to newly developed COVID-19 vaccines, centers are encouraging vaccination. However, at the time of the survey, only a few centers were requiring vaccination prior to transplant for waitlisted candidates.

Management of vaccination in organ transplant recipients is problematic as immunosuppression may reduce the efficacy of the vaccine. Based on a recent report of 187 solid organ transplant recipients, the first dose of two dose vaccine series were shown to be safe, with no reports of rejection, rare systemic reactions such as fevers and chills, and slightly more than baseline headache, fatigue and myalgias.[23] However, immunogenicity after a single dose of mRNA vaccine was low, with spike protein antibodies detectable in only 17% of transplant recipients versus 100% of healthy subjects 14-21 days after vaccination.[24] Two studies showed anti-spike protein response rates of 37.5% and 58.8% following two doses of the mRNA vaccine BNT162b2, with both studies showing significantly lower antibody titers in organ transplant recipients.[25,26] The low immunogenicity after transplant supports AST recommendations on preferential vaccination of potential transplant recipients prior to transplantation. However, this recommendation needs to be balanced against the risk of delaying transplant. As less than 50% of the US population has received one dose to date, it is likely that this will be an issue for many additional months.

Prolonged viral shedding in patients with end-stage kidney disease presents a clinical management challenge for transplant clinicians. In a recent study of routine screening of patients in a dialysis facility, 33% of patients with a positive test were completely asymptomatic.[27] Thus, these patients would not be recognized by clinical signs prior to presenting for transplant. Initially, out of caution, the AST and others recommended delaying transplant until the candidate (or living donor) had two negative tests.[28] With increased knowledge of the clinical course and evidence that viral shedding alone does not appear to correlate with adverse outcomes in asymptomatic non-transplant patients, one third of centers are proceeding with transplant after a predefined waiting period. The safety of this practice has not been firmly established.

Our study has limitations inherent to the survey study design, such as potential for recall bias. The findings represent practices as they are reported; we cannot verify how accurately the reports represent actual practice at each program. Respondents were identified by online outreach to U.S. transplant professionals, and not all programs are represented. However, the 37.2 % response rate is higher than many contemporary studies of transplant program practices (where response rates in 30%-range are common),[15,29,30] likely reflecting the strong community interest in the topic, and the responding centers represent 51.1% of adult kidney transplant volume in the period. These survey data reflect the opinions and experiences of the respondents at the time of completion, and given the rapidly dynamic nature of the COVID-19 pandemic, may not be reflective of subsequent practice and when COVID-19 vaccines are more widely available. This survey was designed in the context of a standard two-dose vaccine course and did not specifically inquire about management of patients who receive the one dose vaccination regimen.

In conclusion, transplant programs are encouraging vaccination but are not routinely delaying deceased donor transplant to complete a full vaccination course at this time. While the majority of transplant candidates with asymptomatic infection and no documentation of infection onset date are deferred, up to one third of centers are transplanting patients with documented infection and asymptomatic shedding. Additional research is needed to determine the optimal timing of COVID-19 vaccinations for transplant candidates and recipients, and to optimize COVID testing practices that provide safe access to transplantation for fully vaccinated and was well as unvaccinated patients, but do not unnecessarily delay transplant procedures.

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Data Availability Statement

Data availability is limited to aggregate summaries as reported, based on IRB requirements.

FIGURE LEGENDS

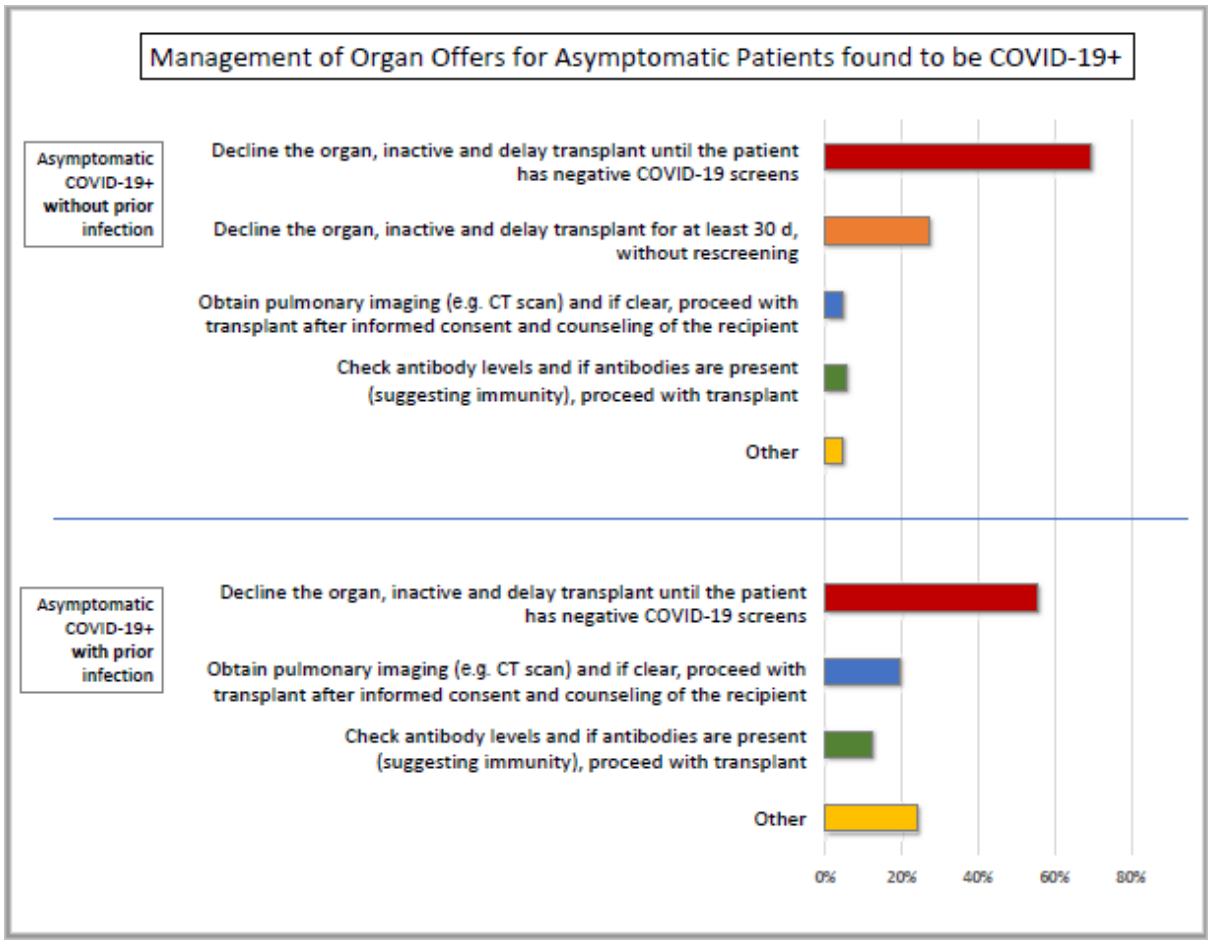

Figure 1. Management of organ offers for asymptomatic kidney transplant candidates found to be COVID-19+.

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Table 1. Characteristics of survey respondents

Role in Transplant Program (N=92)	**% (n)**
Transplant Surgeon	43.5% (40)
Transplant Nephrologist	39.1% (36)
Coordinator	4.3% (4)
Administrator	1.1% (1)
Pharmacist	2.2% (2)
Other	8.7% (8)

Table 2. Assessment of candidate vaccination status at organ offer

How do you educate your kidney transplant candidates regarding acceptance of COVID-19 vaccine, when available? (N= 92)	% (n)
We encourage vaccination on the waiting list and prior to planned living donor transplant	93.5% (86)
We counsel that benefits and risks are uncertain in the transplant population and defer to patient preference	30.4% (28)
We request that patients contact the transplant center after receiving the vaccine	46.7% (43)
Other	10.9% (10)
How do you consider candidate vaccination status with regard to transplant acceptance for patients on deceased donor waiting list who are **not-highly sensitized** (cPRA< 80)? (N= 92)	% (n)
Inactivate patients until they receive a complete two-dose vaccine course	1.1% (1)
Inactivate patients after the first dose and reactivate ~4 weeks after the second dose	6.5% (6)
Accept organs for unvaccinated patients and vaccinate 4-12 weeks after transplant	83.7% (77)
Accept organs for patients after the first vaccine dose and delay the second dose of vaccine for 4-12 weeks posttransplant	51.1% (47)
Other	13.0% (12)
How do you consider candidate vaccination status with regard to transplant acceptance **for highly sensitized** (cPRA>=80) patients on deceased donor waiting list? (N= 92)	% (n)
Inactivate patients until they receive complete two-dose vaccine course	0.0% (0)
Inactive patients after the first dose and reactivate ~4 weeks after the second dose	7.6% (7)
Accept organs for unvaccinated patients and vaccinate 4-12 weeks after transplant	80.4% (74)
Accept organs for patients after the first vaccine dose and delay the second dose of vaccine for 4-12 weeks posttransplant	56.5% (52)
Other	10.9% (10)

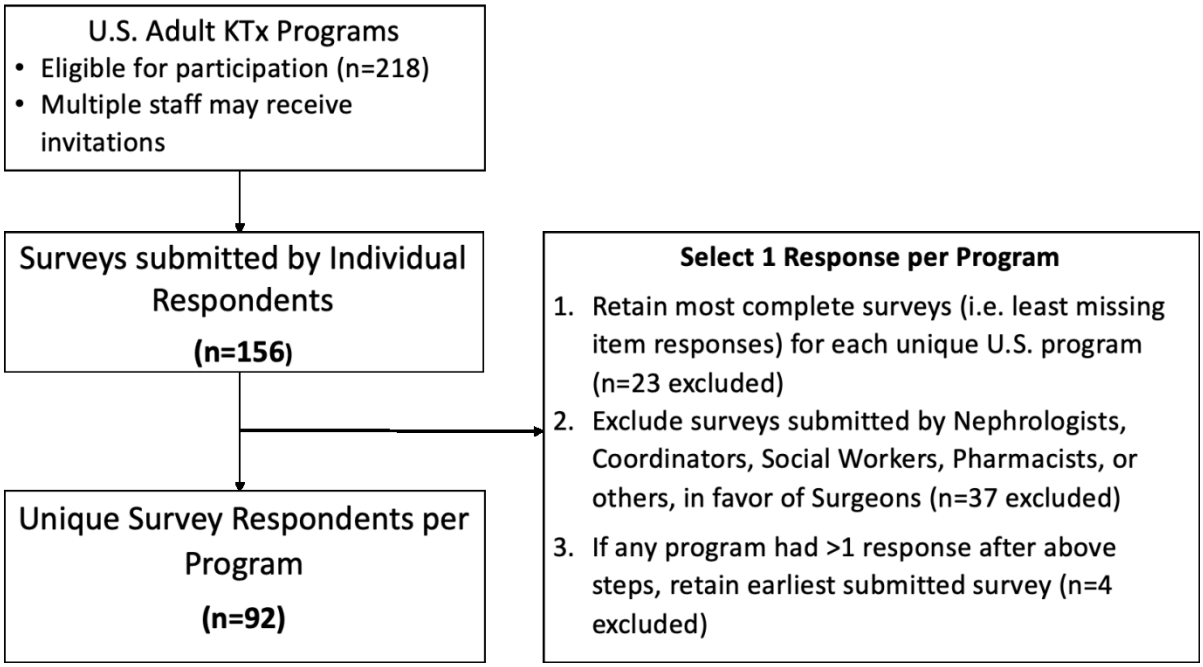
'N=' Indicates the item denominator, based on number of respondents, and accounting for contingent responses

Table 3. Education and coordination of COVID-19 vaccination in transplant candidates and recipients

How are you tracking vaccination status of candidates on your waiting list? (N= 91)	% (n)
Asking patient at time of organ offer	65.9% (60)
Asking all listed patients to update their coordinator after vaccination	62.6% (57)
Directed inquires by program staff	23.1% (21)
Other	11.0% (10)
For those not vaccinated prior to transplant, how long after deceased donor transplant do you recommend recipients wait to receive their first dose of COVID-19 vaccination? (N= 92)	% (n)
0-2 weeks	1.1% (1)
>2-4 weeks	1.1% (1)
>4-8 weeks	43.5% (40)
>8 weeks	53.3% (49)
How long is your center waiting after completion of a recipient's vaccination to schedule a living donor kidney transplant (N= 92)	% (n)
0-2 weeks	12.0% (11)
>2-4 weeks	53.3% (49)
>4-8 weeks	29.3% (27)
>8 weeks	4.3% (4)

Supplemental Digital Content

Figure S1. Response Selection Algorithm



Survey Questions	**Response Format**	**Response Options**
What is your center's 4-character UNOS code?	Dropdown Menu	• UNOS Code
If you work at a non-U.S. center, where do you practice?	Text Entry	
What is your role at your transplant center?	Single Answer	• Transplant Surgeon • Transplant Nephrologist • Coordinator • Social Worker • Administrator • Pharmacist • Other
How do you **educate your kidney transplant** candidates regarding acceptance of COVID-19 vaccine, when available?	Select all that apply	• We encourage vaccination on the waiting list and prior to planned living donor transplant • We counsel that benefits and risks are uncertain in the transplant population and defer to patient preference • We request that patients contact the transplant center after receiving the vaccine • Other
How do you consider candidate vaccination status with regard to transplant acceptance for patients on deceased donor waiting list who are **not-highly sensitized** (cPRA< 80)?	Select all that apply	• Inactive patients until they receive a complete two-dose vaccine course • Inactivate patients after the first dose and reactivate ~4 weeks after the second dose • Accept organs for unvaccinated patients and vaccinate 4-12 weeks after transplant

		• Accept organs for patients after the first vaccine dose and delay the second dose of vaccine of 4-12 weeks posttransplant • Other
How do you consider candidate vaccination status with regard to transplant acceptance **for highly sensitized** (cPRA>=80) patients on deceased donor waiting list?	Select all that apply	• Inactivate patients until they receive complete two-dose vaccine course • Inactivate patients after the first dose and reactivate ~4 weeks after the second dose • Accept organs for unvaccinated patients and vaccinate 4-12 weeks after transplant • Accept organs for patients after the first vaccine dose and delay the second dose of vaccine of 4-12 weeks posttransplant • Other
How are you **tracking vaccination status** of candidates on your waiting list?	Select all that apply	• Asking patient at time of organ offer • Asking all listed patients to update their Coordinator after vaccination • Directed inquires by program staff • Other
How **long** is your center waiting **after completion** of a recipient's vaccination to schedule a **living donor kidney transplant**?	Single Answer	• 0-2 weeks • > 2-4 weeks • > 4-8 weeks • > 8 weeks
For those not vaccinated prior to transplant, how long after **deceased donor transplant** do you recommend recipients wait to receive their first dose of COVID-19 vaccination?	Single Answer	• 0-2 weeks • > 2-4 weeks • > 4-8 weeks

		• > 8 weeks
For **asymptomatic** patients called in for deceased donor transplant **without prior documented COVID-19** infection and **positive nasopharyngeal swabs**, which of the following best describes your current practice?	Select all that apply	• Decline the organ, inactive and delay transplant until the patient has negative COVID-19 screens • Decline the organ, inactivate and delay transplant for at least 30 days, without rescreening • Obtain pulmonary imaging (e.g. CT scan) and if clear, proceed with transplant after informed consent and counseling of the recipient • Check antibody levels and if antibodies are present (suggesting immunity), proceed with transplant • Other
For **asymptomatic** patients called in for deceased donor transplant with **prior documented COVID-19 infection (> 30 days)** and **positive nasopharyngeal swabs,** which of the following best describes your current practice?	Select all that apply	• Decline the organ, inactive and delay transplant until the patient has negative COVID-19 screens • Obtain pulmonary imaging (e.g. CT scan) and if clear, proceed with transplant after informed consent and counseling of the recipient • Check antibody levels and if antibodies are present (suggesting immunity), proceed with transplant • Other