

Current landscape of kidney allocation: Organ procurement organization perspectives

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Abstract

Organ procurement organizations (OPOs) play a central role in the recovery, preservation, and distribution of deceased donor kidneys for transplantation in the United States. We conducted a national survey to gather information on OPO practices and perceived barriers to efficient organ placement in the face of the new circle-based allocation and asked for suggestions to overcome them. Of the 57 OPOs, 44 responded (77%). The majority of OPOs (61%) reported barriers to obtaining a kidney biopsy, including lack of an available pathologist. Most OPOs (55%) indicated barriers to pumping owing to a lack of available staff and transportation. Respondents agreed or strongly agreed that the new allocation system has worsened transportation challenges (85%), increased provisional acceptances of kidneys (66%), increased communication challenges with transplant centers (68%), and worsened the efficiency of organ allocation (83%). OPO-suggested solutions include making transplant centers more accountable for inefficient selection practices, developing reliable transportation options, and removing the requirement for national sharing. These findings underscore the need to examine closely the trade-offs of the new allocation system with respect to costs, organ ischemia, and discard. These findings may help inform practice and

Beatrice P. Concepcion and Meera Harhay contributed equally to this study.

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policy for overcoming transportation barriers and improving the efficiency of organ placement.

KEYWORDS

barriers, deceased donor kidneys, organ allocation, organ procurement organizations

1 | INTRODUCTION

Although kidney transplantation is the optimal treatment for end-stage kidney disease (ESKD), the limited supply of organs has meant that thousands of ESKD patients die each year before they can receive a transplant. In the United States, Organ Procurement Organizations (OPOs) are the cornerstone of organ recovery for deceased donor kidney transplantation. OPOs are directly responsible for identifying potential deceased donors, communicating with grieving families, managing, and testing donors, and coordinating organ recovery, preservation, and transportation to transplant centers. The marked geographic disparities in waiting time to transplant^{1,2} and the high rates of organ discard in the United States³ has led to major policy changes. Indeed, one of the key provisions of the 2019 Advancing American Kidney Health Executive Order was to revise the metric used to assess performance of OPOs and certify only those that meet certain threshold for donation and transplant rates.^{4,5} In parallel with provisions to increase transparency around OPO performance, efforts to mitigate differences in transplant wait time has led to a change in the kidney allocation algorithm by the Organ Procurement and Transplantation Network (OPTN). Under the new policy deceased donor kidneys are offered first to candidates listed at transplant centers within 250 nm of the donor hospital instead of transplant centers located within the arbitrary boundaries of a donation service area (DSA).⁶ Transplant candidates receive proximity points based on the distance between their transplant center and the donor hospital. As a result, OPOs work with several transplant centers outside of their DSA. Experts have opined that this policy change will have profound impacts on deceased donor kidney organ recovery, transportation, and preservation, resulting in longer cold ischemia times, higher delayed graft function and lower utilization rates.⁷ Considering the new and existing challenges to efficient and equitable organ allocation,⁸ OPO, transplant center, and patient perspectives are needed to improve donation and transplant systems and processes. Our survey focuses on the OPO's perspectives.

A better understanding of the current landscape of organ recovery and allocation processes from the OPO perspective can help all stakeholders identify areas for policy improvements and enhanced support. Therefore, we conducted a national survey study with the following aims: (1) understand current OPO practices and perceived barriers surrounding procurement biopsy, machine perfusion, and preliminary crossmatching, (2) elucidate OPO perspectives on barriers to organ placement, and (3) assess potential impacts of the new circle-based allocation system on OPO practices. Using qualitative data from the survey, we also identified key areas in the current allocation

system that require attention and possible solutions from the OPO perspective.

2 | MATERIALS AND METHODS

2.1 | Survey design

The survey instrument was developed by the study authors which included OPO leadership, transplant center surgeons and transplant center nephrologists. Additional feedback was obtained from members of the National Kidney Foundation Workgroup on Understanding Delayed Graft Function to Improve Organ Utilization and Patient Outcomes (NKF DGF Workgroup). The survey questions were developed based on clinical experience, available literature, and the aims of the study. The final survey comprised of 26 questions (Table S1). Survey items included multiple-choice, multiple select, and free-text responses. Participants were queried in which OPO they practice and their role. Participants were asked about practices and perceived barriers on hypothermic machine perfusion (or pumping), perceived barriers to performing a procurement kidney biopsy, practices, and perceived barriers on preliminary crossmatches, and practices after organ procurement including transportation and expedited placement of organs. Practices for procurement biopsies were not surveyed as this topic has already been previously studied.⁹ Participants were also asked about perceptions of how pumping and biopsy practices have changed since the implementation of the new circle-based kidney allocation system on March 15, 2021. In addition, participants were asked in a Likert scale format how strongly they agreed or disagreed with statements regarding the impacts of the new circle-based allocation system. Finally, open-ended responses were sought with regards to perceived impacts of the new allocation system on OPO practices, and any recommendations to improve timely organ assessments and placement.

This study was approved by the Vanderbilt University Institutional Review Board (#211653). The clinical and research activities reported are consistent with the principles of the Declaration of Istanbul, as outlined in the Declaration of Istanbul and Organ Trafficking and Transplant.

2.2 | Participants and survey administration

Personnel of OPOs ($N = 57$), including but not limited to medical directors, chief operating officers, procurement directors and perfusionists

were invited to participate in the survey via email. Potential participants were identified from the NKF DGF Workgroup's professional connections, and the survey was emailed through the Research Electronic Data Capture (REDCap) web-based application at Vanderbilt University.¹⁰ Email invitations to the survey were sent through mailing lists and personal invitations. Participants from individual OPO who were unable to answer some or all questions confidently were asked to share the survey with other potential experts at their OPO. Email invitations to the survey were sent to potential participants from October 28, 2021 to January 10, 2022.

2.3 | Statistical analysis

All available free text responses from OPO respondents were included in the qualitative analysis. For the quantitative analysis, each OPO was represented only once. For OPO's with multiple respondents, the respondent with the highest percentage of questions answered was selected. If there were multiple respondents with the same percentage of questions answered, the respondent who completed the survey first was selected. Surveys that were <50% complete were omitted. These inclusion criteria were specified a priori. The data from Scientific Registry of Transplant Recipients¹¹ from 7/1/2020 to 6/31/2021 was used to compare the location, volume, kidney donation rate, and percentage of donation after cardiac death (DCD) donors over total donors (%DCD) between OPOs that did and did not respond to our survey. To better characterize OPO responses based on their volumes and the types of kidneys they procure, we categorized OPOs as being a high or low volume OPO based on number of eligible donors and utilized the 50th percentile as the delineation between a high or low volume OPO. Similarly, we categorized OPOs as having a high or low percentage of DCD/total donors (%DCD) and utilized the 50th percentile as the delineation between a high or low %DCD OPO.

Responses to each survey question were described by percentages and frequencies or means and ranges, as appropriate. 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. Likert scale responses were described among all respondents as one group, and also analyzed based on whether the respondent belonged to a high or low volume OPO, and a high or low %DCD OPO.

Respondents also commented on two open-ended questions: the first asked to identify challenges related to the new circle-based allocation system, and the second asked for recommendations to improve the allocation process. Three authors including one OPO representative reviewed respondent comments to identify common and contrasting themes and patterns. Respondent comments were additionally analyzed based on whether the respondent belonged to a high or low %DCD OPO. We purposively selected exemplar responses to provide in-depth insight on the quantitative findings around pre-specified barriers to allocation. We also identified themes related to recommended process improvements. All analyses were performed using STATA SE version 15.0 (StataCorp, College Station, TX).

3 | RESULTS

3.1 | Survey participants

There were 59 responses to the survey. There were 39 responses with responses to open-ended questions and all were included in the qualitative analysis. For the quantitative analysis, 2 responses had <50% questions answered and were excluded. Of the remaining 57, 31 responses were from OPO's with one respondent and 26 responses from OPO's with multiple respondents. Of the OPO's with multiple respondents, eight responses were excluded as there was a response from the same OPO with a higher percentage of questions answered and five responses were excluded as there was an earlier response from the same OPO. In total, 44 of the 57 OPO's in the United States were represented in the survey (response rate 77.2%) and included in the quantitative analysis. The number of recipients of the email invitation could not be ascertained because the survey was distributed through email mailing lists. Figure S1 shows the respondent inclusion criteria.

The characteristics of OPO's with respondents compared to non-respondents are shown in Table S2. The volume/size, kidney donation rates, and % DCD of OPO's were similar among respondents and non-respondents. All United Network for Organ Sharing (UNOS) Regions (1-11) were represented in the survey. The roles in the OPO of respondents are listed in Table S2. Half of the respondents were procurement directors of their OPO's.

3.2 | Pumping practices and barriers

Most (77%) indicated that their OPO pumps kidneys at least occasionally (>25% of the time) as shown in Figure 1A. The indications for pumping kidneys are shown in Figure 1B. The most frequently cited indications for pumping kidneys were donation after circulatory death (DCD) kidneys (79%), transplant center request (70%), kidney donor profile index (KDPI) >85% kidneys (66%), elevated creatinine (66%), and expected prolonged cold ischemic time (59%).

Perceived barriers to pumping kidneys are listed in Table 1. Fifty-five percent OPOs reported barriers to pumping, the main reasons were lack of availability of staff (34%) and transportation (23%). The number of pumps available and cost were cited as barriers by a minority (16% and 14%, respectively).

3.3 | Biopsy barriers

Perceived barriers to OPO performing a biopsy are listed in Table 1. Sixty-one percent of OPOs cited at least one barrier, with lack of an available pathologist (32%) and lack of ability to process the specimen (14%) as the most frequently cited. Burden on staff was cited by four OPOs (9%) and cost was cited by one OPO (2%).

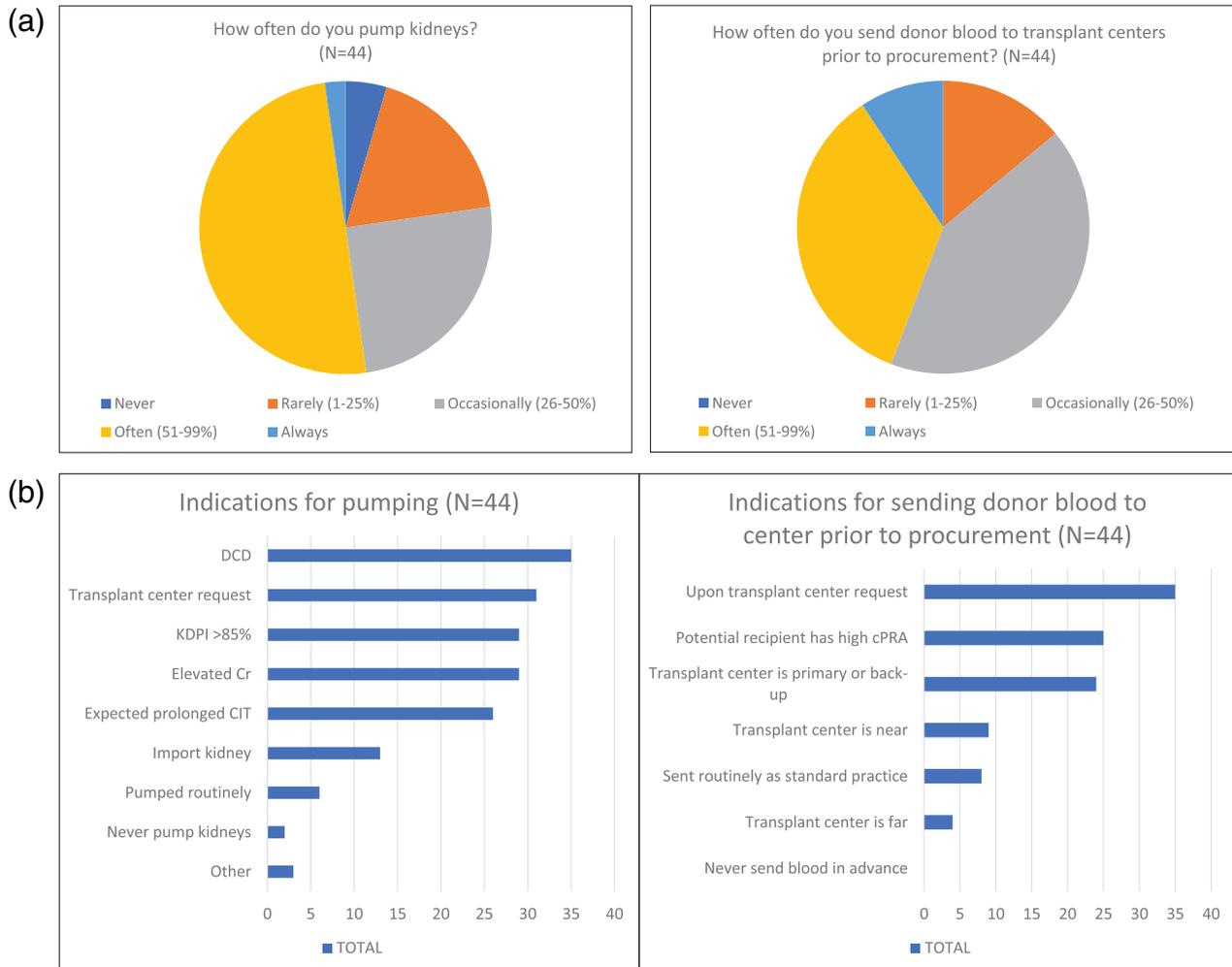


FIGURE 1 (A) Biopsy and preliminary crossmatching practices. (B) Indications for pumping and sending donor blood to centers prior to procurement.

3.4 | Preliminary crossmatch practices and barriers

Most (84.1%) OPOs reported that they send donor blood to transplant centers prior to procurement at least occasionally (>25% of the time) (Figure 1A) and did so most frequently on request by the transplant center (79%), the potential recipient has a high calculated panel reactive antibody (57%), the transplant center is primary or back-up (54%). (Figure 1B).

Perceived barriers to sending donor blood to transplant centers prior to procurement are listed in Table 1. The most frequently cited barriers were lack of available transportation (66%) and not enough time to send the sample (50%). Cost (16%) and burden on staff (9%) were also cited as barriers by respondents.

3.5 | Transportation and expedited placement

The majority (85%) answered that they have had organs rejected or discarded due to unavailable flight schedules or closed cargo hours, including 24% reported that such discards occurred in

10%–25% of procurements. More than half of OPOs (55%) answered that they rarely (1%–25% of the time) allocate kidneys out of the normal allocation process to expedite placement.¹² Thirty-one percent of respondents reported that they do this occasionally (26%–50% of the time) or often (51%–99% of the time).

3.6 | Impact of the new circle-based allocation system

When asked about perceived changes on pumping and biopsy practices with the new circle-based allocation system, OPOs answered that there has been increased pumping of kidneys (39%), increased pumping followed by cold storage (28%), and increased transfers on the pump (26%). Most respondents answered that there have not been changes with regards to biopsy practices (58%).

There were 41 respondents who completed the Likert scale responses to statements pertaining to the impacts of the new circle-based allocation system. These are shown in Figure 2. Most strongly disagreed or disagreed (83%) that the efficiency of kidney placement

TABLE 1 Barriers to pumping, procurement biopsies and sending donor blood prior to procurement.

Barriers	N = 44
Pumping	
No barriers	20 (45)
Availability of staff	15 (34)
Transportation issues	10 (23)
Number of pumps	7 (16)
Cost	6 (14)
Lack of transplant center interest	4 (9)
Other	3 (7)
Not supported by OPO policy/administration	2 (4)
Biopsy	
No barriers	17 (39)
Lack of available pathologist to read	14 (32)
Other	8 (18)
Lack of ability to process specimen	6 (14)
Surgeon preference	4 (9)
Burden on staff to coordinate	4 (9)
Cost	1 (2)
Lack of available surgeon/personnel to perform	2 (4)
Indication is outside of a protocol	0 (0)
Not supported by OPO policy/administration	0 (0)
Sending donor blood to transplant centers prior to procurement	
Availability of flights, courier services or local drivers	29 (66)
Not enough time to send a sample	22 (50)
Cost	7 (16)
Transplant center refusal to accept blood	7 (16)
Too many samples to mail as we mail it for other organ types too	6 (14)
No barriers	5 (11)
Other	5 (11)
Burden on staff	4 (9)
Not supported by OPO policy/administration	0 (0)

Abbreviation: OPO, organ procurement organization.

has increased. Most agreed or strongly agreed that there has been an increase in the use of provisional acceptance of kidneys (66%), that communication with transplant centers has become more challenging (68%), and that organ transportation and challenges have increased (85%). The results of the Likert scale responses when respondents were divided into high or low volume OPOs and high or low %DCD OPOs are shown in Figures S2 and S3. Respondents from high and low volume OPOs responded similarly that they strongly agreed or agreed that there has been an increase in the provisional acceptances of kidneys. Almost half of respondents in the high %DCD group strongly agreed or agreed that DCD kidneys have become harder to place but a third disagreed or strongly disagreed with the statement.

3.7 | Thematic categories of impacts and recommendations

In open-ended responses, OPO respondents provided additional details and context on the efficiency and communication-related challenges they have encountered from the new allocation system (Table 2). Numerous responses indicated concerns that the new allocation system was causing increased cold ischemia time on organs and increased discards. Open-ended comments about transportation barriers revealed difficulties due to unreliable courier services and challenges obtaining flights for organs, possibly exacerbated by the coronavirus 2019 pandemic.

TABLE 2 OPO perspectives on impact on practices and recommendations

Impact on practices of the new circle-based allocation system	
Impact	Exemplar quotes
Efficiency of the allocation process	<p>“...placement is more difficult due to the number of centers initially on list and staff time to place.”</p> <p>“...Increase in request for pumping, donor blood to be sent prior, transfers on pump, complicated logistics.”</p>
Burdens on OPOs	<p>“The volume of work and effort has increased significantly and the outcomes of kidneys transplanted has remained the same.”</p>
Organ utilization	<p>“Our utilization of kidneys is down and discards are up for higher KDPI kidneys since the allocation changes.”</p> <p>“[There has been a] increase in OR or post-OR kidney declines leading to increased cold time and more challenges placing nationally”</p>
Organ acceptance patterns	<p>“... the further down the match run we get centers want to know why others declined; and then may make poor decisions due to groupthink”</p> <p>“The number of provisional yes seems to have gone up while acceptance has not. This adds to CIT which decreases chances of transplant.”</p>
Communication between OPO and transplant program	<p>“The incidence of slow to no response from third parties taking transplant center offers is at a level of great concern. They are sleeping at night; delaying contact with deciding physicians; don't understand the UNOS rules on offers, apparently, especially around acceptance and review time limits.”</p> <p>“Not all transplant programs are prepared for the increase in offers, thus causing delays or using prov yes when there is not intention for transplant—causing additional CIT”</p>
Transportation barriers	<p>“Transportation has become much more difficult especially since local back up has been eliminated.”</p> <p>“Couriers are not reliable (could be current employment market) and we have had to hire our own drivers for ground transportation after we have had to discard kidneys due to unreliable courier system.”</p> <p>“No available flights overnight so it is harder to place kidneys outside of our DSA. Centers that need flights give a hard time about coding out.”</p>
Recommendations to improve timely organ assessments and placement	
Recommendation	Exemplar quotes
Address “Provisional Acceptance	<p>“Removal of “provisional acceptance.” Transplant center either accepts or declines based off of information available.”</p> <p>“Requirement for transplant centers to review the entire offer and not place a Provisional Yes if not seriously considering the organ.”</p> <p>“Provisional yes's are currently meaningless... policies should be put in place that hold centers accountable to certain requirements when entering a provisional yes.”</p>
Accountability for Transplant Program Practices that Impact Efficiency/Utilization/Cost	<p>“Hold programs accountable to their acceptances and reduce late decline of organs.”</p> <p>“[We should] remove ability of transplant centers to receive offers for donor kidneys they do not have a recent history of transplanting (ie... if the transplant center has not transplanted a DCD kidney from a donor > 50yo they should not appear on the match run).”</p> <p>“Force transplant centers to utilize the UNOS filters. Allow OPOs the data to transplant center filters to understand the probability of acceptance of an organ”</p> <p>“All OPOs and Transplant Centers needs to adhere to UNOS policy on offer time limits.”</p> <p>“Need to decrease transplant center requests for biopsy as it often only serves as an out for transplant and thus adding additional CIT.”</p>
National allocation	<p>“Remove requirement to have the Organ Center allocate kidneys nationally.”</p> <p>“[We should] add a 500NM or 750NM circle prior to national placement. Would allow for kidneys that could be driven and more realistically placed.”</p>
Transportation and support for remote decision-making	<p>“[There should be a] unified courier system throughout the United States.”</p> <p>“[Implement] a requirement for virtual cross matches to be completed prior to sending blood to the transplant centers.”</p> <p>“Regional pumping centers may assist in pumping and placement capacity by utilizing efficiencies of scale and standardization.”</p> <p>“Improved digital biopsy options. We tried taking scanners to the hospital OR and they were highly unreliable in transmission of data.”</p> <p>“Eliminate use of third-party coordinators by transplant centers. These services only act as barriers and inhibit communication between the OPO and transplant centers.”</p>
Increase OPO flexibility to facilitate placement	<p>“Allow expedited placement after [a certain] number of hours of cross clamp”</p> <p>“[Allow OPOs] variance to allow priority placement in difficult transport, timing and specific circumstances.”</p> <p>“[We require an] easier system to get “hard to place” kidneys accepted by transplant centers without having to move to aggressive placement and allocation policy violation.”</p> <p>“Identify kidneys at risk for discard and create processes that enable OPO's to get kidneys to centers most likely to utilize faster.”</p>

(Continues)

TABLE 2 (Continued)

Recommendations to improve timely organ assessments and placement	
Recommendation	Exemplar quotes
Reduce discard of marginal kidneys	<p><i>“On marginal kidneys, transplant centers should be offered based off of historical acceptances, this may help us to get through the lists faster, the marginal kidneys are not the ones that can afford added cold time.”</i></p> <p><i>“Utilize data to screen out centers that have not accepted high kdpi kidneys.”</i></p> <p><i>“Use AI to identify earlier in the process where a deceased kidney may most likely be accepted, benefit the recipient the most and get to the center the quickest.”</i></p>

Abbreviation: OPO, organ procurement organization.

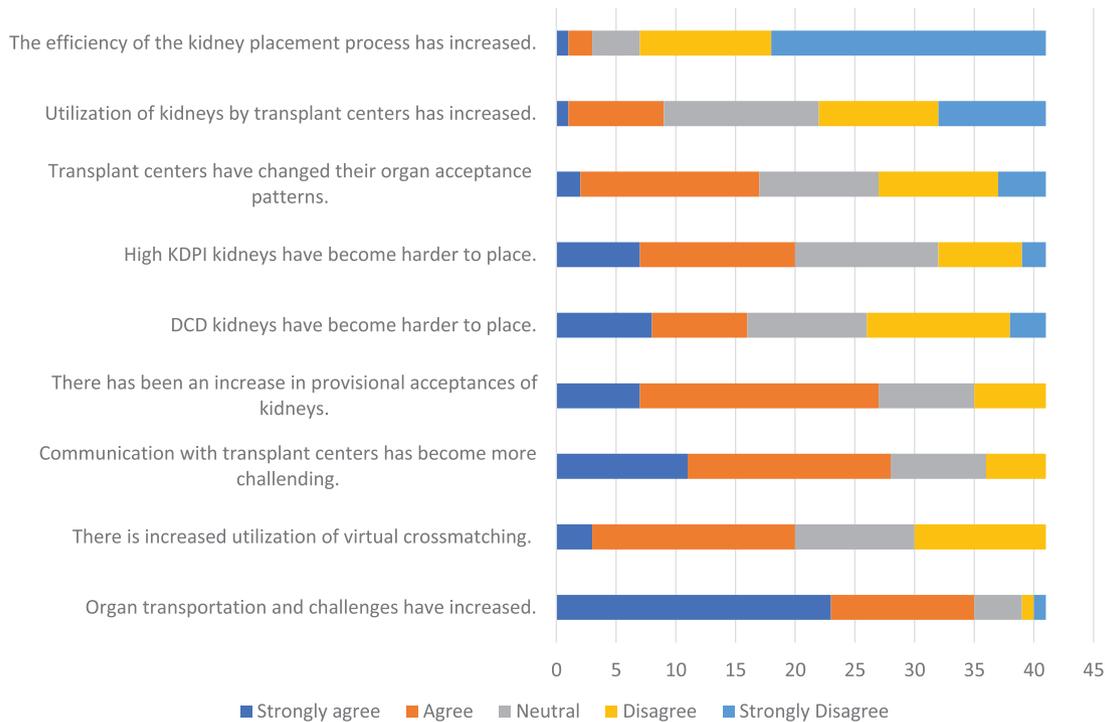


FIGURE 2 Likert scale responses to statements pertaining to impacts of the new circle-based allocation system.

With respect to OPO recommendations for process improvements, we identified six common themes (Table 2): (1) address problematic provisional acceptance of organs; (2) increase accountability for transplant program practices that impact efficiency, costs, and discard; (3) reduce requirements for national allocation; (4) solutions to address transportation barriers and remote decision-making; (5) increase the ability to identify aggressive transplant centers and provide flexibility to OPOs to facilitate organ placement.

4 | DISCUSSION

In this national study of OPO perspectives about the current landscape and challenges of organ procurement and placement in the United States, we identified considerable heterogeneity with respect to OPO practices on indications for hypothermic machine perfusion, and preliminary crossmatches. The majority of OPOs reported that the new

wider circle-based allocation system has exacerbated existing challenges on transportation and preservation of organs. Furthermore, provisional acceptance of organs and transplant center “group-think” were identified as major barriers to efficient organ placement and a potentially addressable cause of organ discard. OPOs suggested process improvements including provision of reliable courier services, more support for machine perfusion, more flexibility in organ allocation, and removal of the requirement for national sharing. Many respondents were concerned that cold ischemia time and organ discard had increased after the implementation of the new circle-based allocation system, underscoring the need for examining organ outcomes following the allocation system changes and identifying opportunities to support OPOs in the mission to increase organ recovery and utilization. Data from the OPTN’s 1-year post-implementation monitoring report is consistent with OPO perceptions.¹³ The report noted an increase in cold ischemia times from a median of 17 h pre-policy to 19 h post-policy and organ discards from 21.8% pre-policy to 24.8%

post-policy across all values of KDPI. Delayed graft function rates were also noted to increase (28.7% pre-policy to 39.9% post-policy) and median sequence number of final acceptor for kidney match runs increased from 9 pre-policy to 18 post-policy. However, the impact of these factors on long-term allograft outcomes has not been assessed due to insufficient time since adoption of the new allocation system. A single-center study assessing the effect of the new allocation system on a large rural transplant program in South Carolina found an increase in cold ischemia time (16 ± 7 h pre-policy vs. 21 ± 6 h post-policy, $p < .001$) and delayed graft function rates (23% pre-policy vs. 40% post-policy, $p = .02$).⁸

The results of our study can help to disentangle some of the OPO and transplant center-level contributions to inefficiencies and geographic variability in the organ acceptance process. OPO performance has been the subject of considerable scrutiny in the recent years, arising from observations of significant variation in organ availability and waiting time between DSA² and the high rate of organ discard in the United States relative to other countries.¹⁴ For example, a study by Lynch and colleagues showed that between 2013 and 2019, the highest performing OPOs recovered 78% more donors than the bottom performing OPOs.¹⁵ To reduce geographic variability in organ availability, increase transparency, and incentivize high-performing OPOs, the Centers for Medicare and Medicaid Service's Final Rule changed in 2021.¹⁶ The change incentivizes top performing OPOs and increases competition, but it also modified the performance metrics to include transplant rate in addition to donation rate. Recent research by Doby et al. showed that prior to the circle-based allocation system change, transplant centers in DSAs of lower-performing OPOs had similar discard rates, higher organ utilization, and higher import of high KDPI kidneys when compared to centers served by higher-performing OPOs. These findings suggested an inverse relationship between organ availability and transplant center aggressiveness,¹⁷ though other research has shown variability in transplant rates between centers in the same DSA and suggests that variations in the probability of transplantation was driven by center practices rather than organ supply differences.^{18,19} In the new circle-based system, OPOs with established relationships with their associated transplant centers and an understanding of their acceptance practices are now being forced to establish new relationships with centers and learn their acceptance practices and preferences.²⁰ Indeed, in the OPTN 1-year monitoring report,¹³ donor kidneys traveled farther, with a median distance from the donor hospital of 121 miles post-policy compared to 68 miles pre-policy, and a smaller proportion of donor kidneys were transplanted within the DSA of the recovering OPO (40% post-policy vs. 71% pre-policy). The circle-based allocation has achieved the desired effect of equalizing geographic variability in kidney transplant. However, some of the inefficiencies in organ placement need to be addressed such as by establishing universal criteria for pumping to combat the increasing cold times similar to recently approved policy on minimum criteria for biopsy.²¹

OPO respondents identified many center practices as potentially problematic including the overuse of provisional acceptances, "group think", and requests for donor biopsies, hypothermic machine per-

fusion, and preliminary crossmatches that often delay allocation decisions and increase cold ischemia time. Our study extends the findings of the study by Emmons et al.⁹ to show that variability in OPO practices extends beyond procurement biopsy to include such practices as sending blood to centers for preliminary crossmatches and indications for machine perfusion. In open-ended responses, several OPO respondents expressed concerns that biopsy requests can dramatically reduce efficiency of allocation and are often used to justify organ turndown, despite prior research suggesting that allograft biopsy interpretations are poorly reproducible²² nor strong predictors of transplant outcomes.²³⁻²⁵ Transportation, particularly during off-hours, was cited as a major barrier to facilitating transplant center requests. These responses might help to explain prior observations that deceased donor organ utilization is lower on weekends and at nighttime.^{26,27} Current transportation mechanisms on commercial air cargo have been also impacted by the pandemic. This creates an opportunity for the transplant community to work with other industries in developing on-demand expedited and reliable distribution systems equipped with live tracking systems.

OPO respondents suggested numerous avenues for improvement in the system, including more flexibility in organ placement to allow OPOs to allocate less than ideal kidneys at aggressive centers, or to utilize local back-ups when a kidney has a prolonged cold ischemic time.¹² Interestingly, close to one third of respondents in the survey reported that they do already allocate kidneys out of the normal allocation process to expedite placement at least >25% of the time. It must be noted, however, that available evidence suggests that these out of sequence organ placements may be exacerbating existing disparities. In a study of match-run data from 2015 to 2019,¹² 1544 kidneys were transplanted from 933 donors with an OPO-initiated allocation exception. Three OPOs were identified as having performed 64% of the exceptions and two transplant centers received 25% of the allocation exception kidneys. Importantly, although donors of these kidneys had a higher median KDPI than donors of non-allocation exception kidneys (median KDPI 70 vs. 46), only 29% had a KDPI >85% and majority did not meet traditional criteria for a marginal kidney. Given the higher reported prevalence of this practice than can be identified in the match-run data, we believe allocation of kidneys outside the normal allocation process requires greater scrutiny, better capture in the data and monitoring to ensure that this practice is used in limited circumstances that allow for improved organ utilization without exacerbating already existing disparities in access to transplantation. Of note, data pertaining to out of sequence allocation data is not available in the OPTN 1-year monitoring report.

Other avenues for improvement in the allocation system that were suggested by OPO respondents included the establishment of a reliable courier service for transport of organs and addressing the increased use of provisional acceptance. Current UNOS initiatives to improve the efficiency of organ allocation may alleviate some of these concerns raised by OPO respondents. First, organ offer filters which have become available on DonorNet since January 2022 and center specific acceptance patterns are available to guide centers to set filter settings. Although this resource can potentially improve allocation

efficiency, it must be noted that these filters can have the untoward consequence of reducing access to transplantation for patients listed at centers who use the filters. Additionally, centers may not necessarily be transparent with their patients regarding the use of the filters raising concerns of the impact of the filters on patient autonomy, and prior use of these filters have not helped improve efficiency suggesting the need for continued evaluation of the new filters.²⁸ Second, two UNOS policies approved in 2022 include the establishment of minimum kidney donor criteria to require a biopsy²¹ and standardization of kidney biopsy reporting and data collection.²⁹ Having minimum objective criteria for kidney biopsy is expected to standardize kidney biopsy usage and minimize late turn-downs. The standardized reporting of kidney biopsies is expected to improve consistency and reliability. Although not a part of the policies, the utilization of digital biopsy readings and “telepathology” is another potential means to improve allocation efficiency. This, however, would require investments in infrastructure and technology for OPOs that have not already invested in this area. Third, tools that can provide real-time information through predictive modeling at time of organ offer may assist centers in making decisions more efficiently with regards to organ acceptance. Finally, like standardizing biopsy practices, national guidance on criteria for pumping and transportation of kidneys on a pump can help address some of the concerns raised by the OPOs. It may also help transplant centers who are rejecting not so ideal kidneys due to the inability of non-local OPOs to transport these kidneys on a pump.

Our study provides insights on the early, real-world impacts of the new circle-based allocation system that aims to reduce geographic disparities in access to kidney transplant. Prior to implementation of the system, experts underscored that this change was expected to dramatically increase the complexity of the organ allocation process; In the new system, for example, the number of centers considered “local” for a given donor offer rose by a median of 17 centers (interquartile range 7–31 centers).⁷ The OPTN 1-year monitoring report¹³ confirms that deceased donor kidneys traveled farther after implementation of the policy, and that more kidneys were allocated outside of the DSA of the recovering OPO. Our study respondents indicated numerous impacts of these changes on OPO workflow, staff administrative burdens, costs, increased transportation requirements, and most concerning, on organ utilization. Respondents identified a worrisome theme of delayed decision-making by transplant centers, leading to prolonged cold ischemia time and an increased likelihood of discard. Indeed, early data¹³ confirm increased cold ischemia times and rates of organ discards post-policy implementation. Overall, the early impacts of the circle-based allocation system as reported by OPO representatives underscore the critical importance of closely monitoring for unintended and untoward consequences on organ utilization and outcomes.⁷

It must be noted, however, that the current system is complex and transplant centers and OPOs have interdependent and overlapping but not identical goals. There may be competing practices by OPOs and transplant centers that accentuate logistical challenges and negatively impact both resource utilization at accepting centers resulting in decreased organ utilization. OPOs report increasing logistical chal-

lenges for pumping and transport, while the transplant centers are now experiencing increasing number of organ offer calls and defaulting to a practice of provisional yes leading to increased discards. Both systems realize there is an opportunity cost to pursuing every single organ procurement and offer which needs to be balanced against limited resources without additional funding to support new mandates and additional staffing. The competing practices by OPOs and transplant centers that accentuate logistical challenges negatively impact both organ and resource utilization at both entities. This conundrum can only be addressed by aligning the goals of OPOs and transplant centers and adopting technological solutions to address increasingly complex problems. For example, creating centralized organ donation centers and transportation systems similar to those utilized by Amazon or FedEx may improve the efficiency of organ placement regardless of OPO size or location while reducing reliance on commercial airlines. Artificial intelligence can support transplant centers with decision making during multiple organ offer calls to reduce staff burn-out. Current OPTN initiatives including but not limited to expedited organ placement by use of filters in DonorNet and including placement efficiency as an attribute in the continuous distribution model may also help address the system wide issues. In summary, OPO, transplant center, UNOS and other regulatory bodies must work collaboratively to put an end to current inefficient and competing practices.

Our study findings highlight the need for better standardization of practices and collaboration beyond the DSA borders across all OPOs and transplant centers to improve organ allocation and distribution in a timely manner (Figure 3). This is exceedingly important as kidney allocation policy moves toward continuous distribution wherein hard geographic boundaries will cease to exist.^{30,31} Issues brought forth by our study's findings should be taken into account as the OPTN and transplant community work towards assigning values for attributes (medical urgency, post-transplant survival, candidate biology, patient access, placement efficiency) that will be used in calculating a patient's composite allocation score and specifically, how much weight *placement efficiency* should have which may have to vary based on organ type such as DCD donor versus deceased brain dead donor and high-KDPI donor versus others.

There are several strengths of our study. To our knowledge, this study is the first to assess OPO perspectives on the current landscape and challenges of deceased donor kidney placement in the new concentric circle-based kidney allocation system. We achieved a nearly 80% response rate, with minimal differences in donor volume, donation rates, and %DCD donors between responders and non-responder OPOs. However, the study should also be considered in the context of its limitations. While there was only one respondent per OPO, the survey was filled out by OPO leadership and therefore should be representative of their practice and challenges. The goal of the manuscript was to understand currently perceived barriers from the OPO perspective. We are unable provide a comparison of perceptions before and after changes in the allocation policy. We also did not provide transplant center perspective therefore findings of the study should be interpreted in the context that only one perspective was provided in a system that has multiple players, that is, OPOs, transplant centers and

Partnership of OPOs, Transplant Centers & OPTN

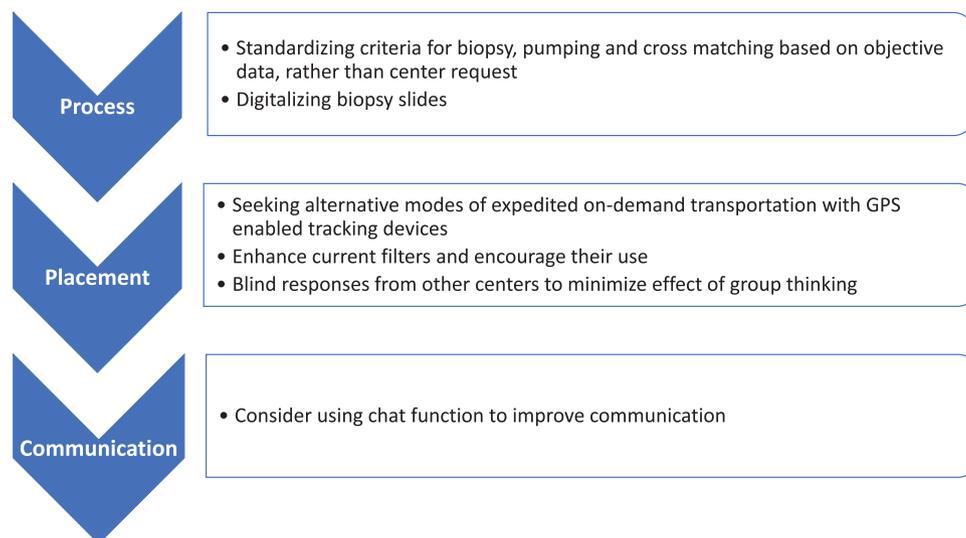


FIGURE 3 Strategies for improving organ placement.

OPTN. The survey also did not inquire about changes and initiatives that OPOs have implemented as a result of allocation changes that could potentially address the barriers and challenges they reported. We had proportionally higher number of non-responders from the northeast, so it is possible that our findings are not representative of practices and barriers in that region. Furthermore, our study assessed OPO perspectives during an ongoing pandemic, which is exacerbating some challenges such as transportation. Surveillance of the impacts of allocation policies should be ongoing and include input from all major stakeholders including OPOs, transplant centers, and patients.

In conclusion, this national study found substantial variability in OPO practices surrounding preliminary crossmatch, and machine perfusion. Respondents identified unreliable transportation options, unavailability of staff and delayed decision-making by transplant centers as major barriers to efficient organ utilization. It is likely that the new circle-based allocation system has further exacerbated the existing problem of suboptimal resources and bandwidth including lack of adequate infrastructure, transportation, and administrative staff. Respondents also identified negative impacts of the new system on organ cold ischemia time and utilization that will require continued attention and surveillance. OPOs recommend standardized criteria for biopsy, pumping and cross-match, along with exploring other options for reliable expedited transport of organs. Open and ongoing discussions between transplant centers, OPOs and the OPTN are essential to overcome logistical challenges posed by the new circle-based allocation system. Our survey results highlight the barriers perceived by the OPOs and should be considered as allocation moves toward a continuous distribution model. National policies and solutions should ultimately meet the goals set by the Advancing American Kidney Health Initiative.

AUTHOR CONTRIBUTIONS

Beatrice P. Concepcion, Meera Harhay, Mona D. Doshi: Concept/design, Data analysis/interpretation, Drafting article, Critical revision of article, Approval of article, Statistics, Data collection. Jay Ruterbories, Jan Finn, Alex Wiseman, Matthew Cooper, Sumit Mohan: Concept/design, Data analysis/interpretation, Critical revision of article, Approval of article, Data collection.

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CONFLICT OF INTEREST STATEMENT

The authors have no relevant conflict of interest to disclose

DATA AVAILABILITY STATEMENT

Data is available upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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