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Public Comment Proposal

Guidance on Effective Practices in Broader Distribution

OPTN/UNOS Operations and Safety Committee

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Contents

Guidance on Effective Practices in Broader Distribution

Affected Policies: *N/A*
Sponsoring Committee: *Operations and Safety*
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Executive Summary

The OPTN/UNOS Operations and Safety Committee created a guidance document to provide effective practices as well as operational and process recommendations. The intent of this guidance is to help OPTN members adapt to policy changes that address the broader distribution of organs. These allocation changes impact all members in the organ donation and transplantation community and will require operational changes to increase the efficiency of organ allocation, donor and recipient matching, transportation logistics, and organ recovery.

The guidance document is intended to serve as a resource for OPTN members. The scope and content should reflect collaboration between OPOs, transplant hospitals, and histocompatibility labs, taking into consideration their needs and best practices.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Operations and Safety Committee is requesting feedback on collecting additional data on the “mode of transportation” for organs. This will help provide data for future broader distribution discussions.

- Does the transplant community support additional data collection necessary for OPTN Committees to evaluate the logistical impact of broader distribution? For example, collecting information on the “mode of transportation” used to transport organs.

What problem will this resource address?

Concerns about cost and transportation were raised during the 2015 Liver Forum[1] and continue to be a concern as noted by the numerous comments received during recent liver[2] and lung[3] proposals. In response to proposed organ allocation policy changes that address broader distribution and the removal of DSAs and regions as units of allocation, there was a recommendation from the Ad Hoc Geography Committee to create a guidance document that provides information and options for best practice processes among OPOs and transplant programs. The Committee recognized that there was limited data on cost and transportation as well as guidance to address logistical challenges that might occur with broader organ distribution.

Why should you support this resource?

This guidance document was created to help transplant programs and OPOs in their transition to broader distribution. It was developed in consultation with relevant subject matter experts, stakeholders, and OPTN staff. The Operations and Safety Committee has created this guidance document to serve as a resource to provide recommendations to the overall allocation process.

How was this resource developed?

The Ad Hoc Geography Committee was created in December 2017 as a first step in the comprehensive look at organ distribution across all organs. On June 28, 2018, the Operations and Safety Committee was briefed on recent events regarding liver allocation policies and the plan to address the use of DSAs and regions in other allocation policies. The Committee discussed the impact and potential actions that could affect all of the other organ systems such as logistics and cost.

This guidance was developed at the request of the Ad Hoc Geography Committee. It is anticipated that the elimination of DSAs and regions will expand to other organs and result in an increase in travel and logistical challenges. The Committee was asked to provide recommendations for the overall allocation process as it relates to broader distribution from an operations and safety standpoint.

The Committee created two subcommittees with participation from all committee members. The Committee Chair led a subcommittee group charged with analyzing the logistics of increased travel. This subcommittee developed a questionnaire to assess the current state of availability of planes and pilots. The Committee finalized the questionnaire before reaching out to all 58 OPOs to collect the information. Once the information was collected, an analysis was done using average travel times to determine ischemic time barriers or limits. The final report was included as Appendix C in the Liver and Intestinal Organ Transplantation Committee's briefing paper[4] to the Board of Directors in December 2018.

The Vice Chair led the second subcommittee, which focused on the logistics of offer acceptances, hard backups, and new relationships with broader distribution. Committee members communicated frequently between meetings to develop a draft and identify challenges associated with broader distribution. These discussions led to the identification of topics and the development of this guidance document.

The Committee requested input from an aviation expert to discuss the current shortage of pilots and forecasted trends in aviation and OPO logistics. The Committee also collaborated with the Ad Hoc Disease Transmission Advisory and Histocompatibility Committees to assist with the sections addressing seasonal and geographical disease testing as well as histocompatibility considerations with broader distribution. These discussions, in addition to data analysis and review of the questionnaire data, provided the Committee with information to include in the guidance document. Committee members worked together in groups on assigned sections of the document that they drafted and later developed into one

[1] https://optn.transplant.hrsa.gov/news/liver-forum-and-committee-update-june-2015/
[2] https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf
[3] https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf
[4] https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf

document with recommendations based on the information that had been gathered. The Committee met frequently to review and provide feedback on the document until agreeing on a final draft.

How well does this resource address the problem statement?

This guidance addresses the concerns raised about the operational and safety challenges anticipated from changes in allocation policies. It provides a resource to assist members in identifying effective practices and promoting collaboration and efficiency needed to adapt to broader distribution allocation processes. This guidance document addresses the following topics:

- Building relationships to optimize operations
- Transportation resources
- Streamlining communications and information distribution
- Histocompatibility considerations with broader geographic organ distribution
- Organ allocation procedures
- Recognizing seasonal and geographic endemic infection in organ donors
- Establishing the time of organ recovery
- Organ procurement surgeon models
- Procurement team staffing models
- Organ procurement related billing
- Establishing fair market value for organ procurement activity
- Organ procurement malpractice coverage considerations
- Procurement team staffing models
- Data metrics

Which populations are impacted by this resource?

Collaboration and best practices could potentially impact transplant candidates and donors by ensuring organ utilization is not negatively impacted by broader distribution.

How does this resource impact the OPTN Strategic Plan?

1. *Increase the number of transplants*: There is no expected impact to this goal.
2. *Improve equity in access to transplants*: There is no expected impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes*: There is no expected impact to this goal.
4. *Promote living donor and transplant recipient safety*: There is no expected impact to this goal.
5. *Promote the efficient management of the OPTN*: This guidance promotes the efficient management of the OPTN by providing information to members without adding additional requirements.

How will the OPTN implement this resource?

If this document is approved, it will be available through the OPTN website.

How will members implement this resource?

This guidance does not require any member action. This document will be available as a reference on the OPTN website pending approval by the Board of Directors.

Will this resource require members to submit additional data?

No, this guidance will not require additional data collection. However, it does contain a recommendation to update current potential transplant recipient (PTR) codes to improve data collection.

How will members be evaluated for compliance with this resource?

Guidance from the OPTN does not carry the weight of policies or bylaws. Therefore, members will not be evaluated for compliance with this document.

Guidance Document

Guidance on Effective Practices in Broader Distribution

Introduction

Changes to organ distribution will impact all members in the organ donation and transplantation community. These changes will necessitate operational changes to increase the efficiency of organ allocation, donor and recipient matching, transportation logistics, and organ recovery. This guidance document is intended to provide effective practices and operational or process related recommendations to OPTN members in an effort to adapt to broader distribution and increase collaboration and efficiency.

Building Relationships to Optimize Operations

As the broader distribution of organs becomes reality, there is an increased need for relationship building and collaboration between OPOs and transplant hospitals across a broader geographical area than just those that are members within a Donation Service Area (DSA) or OPTN region.

In the past, organ procurement organizations (OPOs) and transplant hospitals focused relationship building and collaboration on the organizations within their specific DSA or Region. Regional consortia were formed in many regions of the country to discuss donation and transplant activity, operational and systematic challenges, process improvements, policy changes, donor management strategies and guidelines, and many other topics relevant to those partnerships, all in an effort to increase organ donation and transplantation.

Broader distribution policies will require organs to be allocated to transplant centers outside of an OPO's DSA with much greater frequency. Forums and mechanisms to build relationships amongst these broader partnerships will be necessary to streamline communications and facilitate discussions about donation process, feedback for improvement, and increased understanding of expectations to serve to reduce the risk of organ wastage and inefficiency of the donation and transplant process.

Progress towards this effort has already begun. In some areas of the country, OPOs have partnered together to share practices, transportation policies, donor processes, feedback on follow-up communications between transplant hospitals and OPOs, and clinical research protocols that may impact organ utilization.

Transportation Resources

Broader geographic distribution of extra-renal organs will require increased air transportation resources to transport organs more frequently than occurs currently. OPOs and transplant hospitals should perform a critical analysis of their available aviation resources to prepare for this change.

A proactive approach to aviation resources (pilots, planes, charter options) is essential, especially given the aviation industry forecasts of pilot availability in the coming years. In 2014, the Government Accountability Office published a report[5] that "confirmed many industry observations concerning the dwindling ranks of qualified pilot candidates, noting that age-mandated pilot retirements and other attrition in the ranks of existing commercial pilots continues to outpace the rate of new hires[6]."

The OPTN Operations and Safety Committee conducted a survey of OPOs and transplant hospitals to determine the current landscape of plane and pilot availability, frequency of aviation delays, lack of availability, and thresholds to use aviation resources rather than ground transportation. The summary and analysis of this questionnaire can be found in **Appendix 1** of this guidance document.

[5] https://nbaa.org/wp-content/uploads/2017/03/gao-study-aviation-workforce.pdf
[6] https://nbaa.org/gao-study-highlights-realities-of-pilot-shortage/

OPOs and transplant hospitals may also wish to adopt and implement a set of minimum aviation operating safety standards, insurance requirements and guidelines that suggest at which distance or ground travel time there is a transition from ground transport to air transport. Such guidelines may reduce the use of valuable aviation resources when they are not truly necessary and have them available for those circumstances when they are critically important.

Streamlining Communications and Information Distribution

Enhancing communications during the organ allocation and transplantation process will be a key component to successful organ recoveries and reduction in organ discard risk. Systems and tools to improve communications throughout the allocation and donor evaluation process should be adopted in a number of areas.

DonorNet® has proved a valuable tool in the allocation process. Since the implementation of electronic notifications of organ offers through DonorNet, OPOs and transplant hospitals have had the ability to share and review donor information in a centralized location and reduced the amount of donor data shared verbally. Organ allocation became more efficient as a result, and now DonorNet serves as an integral tool in the organ donation process. Still, enhancements are needed and become more essential as organs are distributed across DSAs more frequently.

In 2018, operating room (OR) timing was added as a feature to DonorNet (**Figure 1** "Follow Donor"). This enabled OPOs to enter the anticipated OR timing and transplant hospitals to receive updates of that information electronically. Though this was added at the request of DonorNet users, it has not been widely utilized. Similar features should be added to DonorNet that enable the electronic sharing of donor information such as updated clinical data, crossclamp time, recovery times and donation after circulatory death (DCD) related data. Such an update would enable transplant hospitals to be aware of case progress real-time.

Figure 1: DonorNet "Follow the Donor" feature

The benefits of transplant hospitals seeing images of organs or diagnostic studies are obvious. These capabilities should be utilized as frequently as possible to enable key decision makers to make the best assessment possible of the suitability of organs being offered for their transplant candidates. Many OPOs are already utilizing third party file sharing platforms to share donor cardiac catheterizations, chest and abdominal computerized tomography (CTs), bronchoscopies, echocardiograms or other video image files to better enable optimal evaluation of organ function, size and suitability by transplant centers.

In 2012, members of multiple OPTN committees put forth a guidance document to promote effective practices for the photography and sharing of organ photos or biopsy images. This guide is available on the OPTN website at this address:
https://optn.transplant.hrsa.gov/media/1265/donor_liver_resources_201206.pdf

The OPTN recommends DonorNet enhancements that will enable a consistent process for the sharing of post-recovery donor test results from OPOs to transplant hospitals. This could include information as standard blood, sputum and urine cultures, pathology results, or additional infectious disease testing that may have been performed. Currently, there is variability of how post-recovery donor test results are shared from OPOs to transplant center Patient Safety Contacts.

Histocompatibility Considerations with Broader Geographic Organ Distribution

The following guiding principles will be important for OPOs:

1. OPOs should perform human leukocyte antigen (HLA) typing of deceased donors as early as possible in the organ donation process to enable the utilization of HLA when generating match runs. HLA should be available to transplant hospitals considering organs for their candidates so that virtual crossmatches can be performed.
2. After match runs are generated, OPOs should consider prioritizing specimen distribution with transplant centers who have provisionally accepted an organ for a highly sensitized candidate amongst the top of potential candidates for the organ.
3. OPOs may wish to establish systems and processes to share specimens. Effective practices have led to the creation of standardized specimen collection kits to enable distribution of the minimum required specimen while minimizing the amount of blood that is required from the donor.

The following guidance is provided for transplant centers and their HLA lab colleagues:

1. Rely more on virtual crossmatching with retrospective actual (physical) crossmatching. Preserve the requirement for direct, prospective crossmatching for cases in which sensitization is possibly labile and allocation and ischemic time will allow for direct testing.
2. Perform highly effective antibody screenings on recipients. For recipients with recent sensitizing events, hospitals should consider rescreening for antibody on a stat basis as opposed to requiring prospective crossmatch testing. In most cases the testing can be completed within a few hours of sample receipt, a much shorter timeframe than arranging for donor sample to be shipped and tested.
3. Add unacceptable antigens to UNet^{sm} listing for recipients for those antigens which meet institutional definition of positive. Consider mean fluorescence intensity (MFI) strength, cross-reactivity, compliment fixation, etc. Do consider the balance between filtering organ offers and the safety of virtual crossmatches when entering antigen data.

In general, the community should incorporate processes which encourage early testing and distribution and deliberate donor specimen conservation by distribution samples with those centers most likely to receive an organ and will absolutely require a direct prospective crossmatch for safety. Transplant centers and HLA Directors will need to be judicious in their application of direct crossmatching requirements and develop a comfort level with heavier reliance on virtual crossmatching with retrospective confirmatory testing to guide treatment if necessary.

More information on pre-transplant crossmatch requirements can be found at https://transplantpro.org/news/labs/policy-clarification-pre-transplant-crossmatch-requirements/

Organ Allocation Procedures

Efficient organ allocation begins with effective waitlist management by transplant hospitals. Candidates should be accurately listed to reflect the type of donor organs that would be reasonably acceptable. Significant time can be wasted by OPOs and transplant center staff dealing with organ offers to candidates who appear on the match run for a given donor yet are declined due to factors that are able to be filtered at the time of listing. For example, if a candidate will not accept a DCD organ, or an organ from a hepatitis C virus (HCV) nucleic acid testing (NAT) positive donor, or a donor greater than 1000 miles away, then the acceptance criteria should reflect those factors on the waitlist. Imprecise listing results in unnecessary organ offers and increases allocation times.

OPOs should employ a donor data validation step to ensure that accurate donor information is entered into DonorNet at the time of running the match runs to ensure that the appropriate candidates appear on the list. UNOS performs such a validation process each time the Organ Center receives a request to offer organs from the Organ Center. That experience suggests 3% of the time match runs need to be re-generated due to inaccurate donor data entry.

OPOs should refrain from initiating match runs until as close in time as possible to the initiation of the organ allocation process to ensure that the match runs reflect the most up-to-date candidate sequence by medical urgency. Delaying the match run until ready to allocate organs enables the most accurate and up-to-date candidate sequencing.

Once initiating organ allocation, OPOs should make efforts to place each organ with a primary and a back-up candidate. Recently introduced OPTN policy[7] has modified the time frame that transplant centers have to evaluate organ offers. From the time of notification, transplant centers have 1 hour to review the donor information and enter a response as either a provisional yes or refusal. Transplant centers should make an effort to respond not just for the candidate for whom they are receiving the offer but also those candidates further down the match run at their center. This will help streamline the allocation process by reducing unnecessary electronic notifications. This will also enable OPOs to know for which candidates a transplant center may have interest even if they are declining the organ for their top candidate(s).

Policy 5.4.D: Backup Organ Offers states that "OPOs may make backup offers for all organs. Transplant programs must treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ. If a transplant program refuses to consider or does not respond to a backup offer, the offer will be considered refused." It is strongly encouraged that transplant hospitals should seriously consider back-up organ offers with the anticipation that the organ offer may become a primary offer. Since the implementation of DonorNet and electronic organ offer notifications, the "Provisional Yes", at times, may have devolved into a placeholder when the offer is for a backup candidate. Frequently an OPO may have an organ allocated to both a primary and backup hospital only to later have the primary hospital decline for recipient-related reasons and the backup hospital, now primary, decline the offer due to information that had been known since they had entered the "Provisional Yes." This practice can have significant consequences in delaying organ placement and impact the transplantation of suitable organs.

The placement of one organ often impacts the placement of all other organs from that donor, including the placement of multi-organ combinations such as kidney-pancreas, heart/lung or extra-renal organs with a kidney. Since multiple organ allocation occurs on a primary organ match run, transplant centers being offered the other organs following the sequence of other match runs may not be aware of the multiple organ allocation. For example, if a liver is placed with a liver candidate who also requires a kidney, the transplant hospitals being offered the kidneys by way of the kidney match run may not see that the liver candidate also requires a kidney. A kidney center may perceive their candidate as primary for one of the kidneys. Communication and transparency of the allocation plan to transplant centers being offered organs is essential. Many have suggested that the plan and updates regarding allocation be typed into the "Highlights" section of DonorNet so that transplant hospitals are aware of their status in the allocation.

Recognizing Seasonal and Geographic Endemic Infection in Organ Donors

The Ad Hoc Disease Transmission Advisory Committee (DTAC) reviews potential donor-derived disease transmission events reported to the OPTN. A number of potential donor-derived transmission events reported are seasonal and geographically associated. A proportion of the events are severe or cause death. Recognition of disease in donors can be challenging. To minimize the risk of disease transmission, a proportion OPOs have instituted seasonal and geographic screening practices. For example, screening for West Nile Virus is usually performed during the summer and fall seasons. OPOs with a high proportion of foreign-born donors have chosen to screen for Strongyloides and Chagas Disease based on epidemiological risk factors. As new broader distribution policies are implemented, transplant hospitals will need to review the OPO's seasonal and geographic endemic infection screening practices and develop protocols, the goal being to maximize organ utilization and minimize the risk of disease transmission.

[7] https://optn.transplant.hrsa.gov/media/2368/opo_policynotice_20171221.pdf

Establishing the Time of Organ Recovery

Setting the time for the recovery of organs should be an open and collaborative discussion between the OPO and all parties that may be accepting organs from a donor to determine a time that will meet the needs of the OPO, transplant hospitals, donor hospitals and of course the donor families. Ideally adequate time would be provided to all transplant hospitals to:

- Evaluate and consider the organs being offered
- Request additional donor evaluative procedures deemed necessary for an appropriate decision
- Mobilize necessary resources within the transplant hospital
- Enable crossmatching as needed for the intended candidate
- Allow for the logistical needs of the recovery and transport to the donor hospital
- Safely bring in the intended candidates for the transplant procedure

Understanding that there may be unavoidable circumstances or situations that do not allow for adequate time, a collaborative decision as to the timing of organ recovery is preferable to having the timing being dictated by a single party which may place unneeded pressure on all others involved. In such circumstances, inadequate time allowance may result in a transplant hospital's refusal of the organ and a candidate being disadvantaged.

Providing transplant hospitals adequate time to enable organ acceptance with surgical recovery being the goal, the needs of all programs involved may at times result in a transplant hospital having to expedite their processes. The OR time should be set based on the needs of other surgical teams and their candidates, availability of OPO resources, donor hospital resources or donor family time constraints.

Unnecessary delays to perform organ recoveries can have negative consequences that impact organ donation in many ways. Prolonged time in the donor hospital ICU can impact the donor hospital staff's perception of the organ donation process and their support of organ donation in their institutions. Prolonged time in the donor hospital ICU ties up resources that may be available to other critically ill patients at that hospital. Extended time prior to procurement, even with the support of the donor family, can have negative emotional impact on the donor family members and loved ones. Unnecessary delays to complete the organ recovery in a timely manner can have an impact on OPO staffing which has a trickle-down effect on other donor activity in an OPO service area. Donor stability during hemodynamic management for extended periods of time can result in unexpected donor cardiac arrest resulting in a loss of transplantable organs.

Policy 2.14.G: Start Time for Organ Procurement states "After organs have been offered and accepted, recovery teams must agree on the time the procurement will begin. If they cannot agree on the start time for the procurement, the host OPO has the authority to withdraw the offer from the transplant hospital that cannot agree on the start time for procurement."

Organ Procurement Surgeon Models

Transplant centers and organ procurement organizations should evaluate the capabilities of their surgical team to meet the increasing surgical demands expected with greater geographic distribution of organs. There are three (3) common surgical coverage models for procurement-related activity:

- Use of Employed Surgeons
- Use of Affiliated Surgeons
- Non-Employed/Non-Affiliated

Employed surgeons are typically hired and compensated by the transplant center or the organ procurement organization to fulfill the overall surgical needs of the hospital. This model is the most common due to the nature of organ call and its impact on physician productivity. There is also an emerging trend at high-volume centers to hire a dedicated full-time or part-time *Organ Procurement Surgeon (OPS)* to handle the procurement-related needs of their hospitals. This model allows hospitals to increase their ability to accept organ offers, while providing life-balance to their core surgical team.

Affiliated surgeons are not directly employed by the transplant hospital or organ procurement organization but contracted to provide surgical services. This model can be equally successful if alignment language is clear and the relationship is mutually beneficial to the surgeon and transplant hospital. Considerations for administrative-related compensation should be evaluated to ensure that an affiliated surgeon is involved with the quality management and other operational discussion.

Many transplant centers and organ procurement agencies also informally utilize surgeons that are *Non-Employed/Non-Affiliated* to augment their procurement-related staffing needs. This type of arrangement is often based on trust and collegial relationships between surgeons. There is often no formal contract between procuring surgeon and transplant center, and this can lead to a myriad of challenges that should be evaluated closely. Compensation issues related to donor recovery attempts without procurement or recovery should be discussed in advance of any recovery. The skills required to assess an organ are equally important as the surgical technique and experience. Organ recovery requires the skill of a vascular surgeon combined with insights of a transplant surgeon and therefore surgeons should be compensated at reasonable fair market value for their time regardless of the ultimate utilization of the organ.

Procurement Team Staffing Models

Transplant hospitals and OPOs should assess their capabilities with respect to the support of the organ recovery process. With increased geographic distribution, it is expected that organ recovery teams may be susceptible to greater risk of burn-out and fatigue. The Operations and Safety Committee recommends the development of a comprehensive labor model survey to better understand the following in preparation for allocation model changes.

Due to increased air transport of organ procurement teams (OPO staff and surgeons) to perform organ recoveries it is recommended that whenever possible travel of personnel is limited. Transplant hospitals may wish to rely on a local organ recovery surgeon to assess and procure organs on their behalf. It is recommended that transplant hospitals identify surgeon colleagues in neighboring regions that they may trust to perform these recoveries and reduce their air travel.

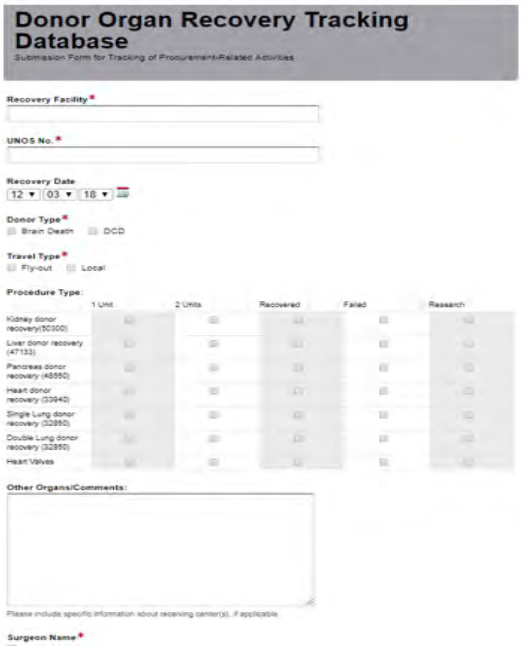
OPOs that provide procurement coordinators/preservationists to accompany recovery surgeons for procurements in neighboring regions may wish instead to request and rely on the perfusion services of the host OPO. With increased geographic distribution, the frequency of these events will increase significantly and OPOs should, when possible, seek the assistance of neighboring OPOs to provide these services rather than increase the number of staff traveling for the recovery to perform tasks that could be performed by the host OPO staff.

Organ Procurement Related Billing

Professional billing for organ procurement services can often be confusing as it does not follow normal claim flow. Costs related to organ procurement are reimbursed on the transplant center's Medicare Cost Report (MCR) and not through conventional means. When an employed surgeon or affiliated surgeon procures an organ, flow of billing information is simple as a charge capture system (paper or electronic) can ensure capture of cost onto MCR. However, when a *Non-Employee/Non-Affiliated* surgeon is involved in the organ donor procurement, the flow of billing information is often interrupted or incomplete.

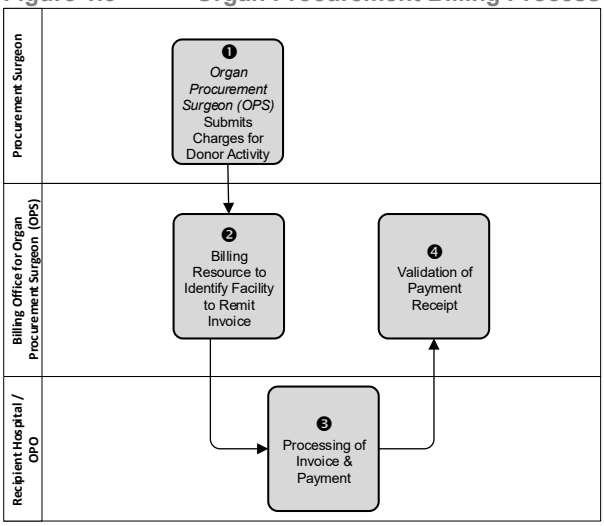
It is the responsibility of a *Non-Employee/Non-Affiliated* surgeon or his/her team to invoice the facility or host OPO that the organ was procured and provide the entity being billed with the key information required for accurate payment (e.g. UNOS ID, organs recovered, facility, etc). For centers that have surgeons that procure on behalf of other centers, the use of a web-based charge submission form is highly recommended as this captures necessary information in real-time to invoice the recipient facility/OPO. See **Figure 1.2**, *Donor Organ Recovery Tracking Form* for an example of a web-based form that can permit submission of charge-related data.

Figure 1.2 Donor Organ Recovery Tracking Form



Minimum variables that should be collected are Donor ID, Date-of-Procurement, Donor Faculty UNOS code, Organ Type, # of Units and general notes. This process of invoicing is complicated and should be mapped-out by all transplant centers that engage in this type of resource sharing. There are four distinct components of the process that should be investigated: 1) Charge Submission, 2) Invoicing, 3) Payment Processing and 4) Payment Receipt Validation.

Figure 1.3 Organ Procurement Billing Process



Charge submission is perhaps the most critical and problem-prone phase of the billing process. Since a limited amount of information regarding organ procurement is documented in the surgical note, centers must ensure there is an effective process to capture necessary detail to invoice the facility or host OPO. In addition, centers should discuss the implications of this type of activity on their accounts payable systems as the efficacy of the invoicing/payment process can have an impact on the relationship building process with the prospect of greater geographic distribution.

OPOs should inform teams arriving from outside their DSA of the process for submitting invoices for organ procurement such as the mailing or email address at their OPO invoices should be sent for payment.

Establishing Fair Market Value for Organ Procurement Activity

As the transplant community prepares for greater geographic distribution of organs, centers and organ procurement organizations will need access to Fair Market Value (FMV) data to establish compensation models for their procurement-related professional activity. Currently there is no national standard for professional reimbursement of donor organ recovery. The committee recommends that Association of Organ Procurement Organization (AOPO) consider the survey of facilities to better understand reimbursement for recovery activity and sharing of collected data. This will be critical to the development of a network of procurement surgeons.

Organ Procurement Malpractice Coverage Considerations

Even though organ transplants occur regularly, transplant procedures remain incredibly serious and complicated. Though the donor family is not likely to seek reimbursement for malpractice-related damages from the procuring surgeon's liability policy, the possibility of a transplant recipient experiencing negative outcomes seeking damages is not unheard of. Identifying donor organ anatomical damage is a critical factor in the transplant process. A recent study, in the *World Journal of Transplantation* indicated that the incidence of organ loss as result of damage to the procured organ to be approximately 0.3%. Surgeons that participate in procurement in a *non-employed/non-affiliated* capacity, are strongly encouraged to evaluate their own malpractice coverage limitations. The following are recommendations with respect to inquiry into the malpractice coverage concern for surgeons that procure in *non-employed/non-affiliated* capacity:

1. Make sure the physicians' current employment contract does not prohibit him/her from moonlighting as procurement surgeon.
2. Does the existing policy cover the surgeon at the non-affiliated facility?
3. Does the policy cover the transplant specialty as it pertains to organ procurement (if non-transplant specialty physician is utilized)?

Data Metrics

Following the implementation of any major change in policy, such as the broader geographic distribution of organs, there is always the need to monitor the effects of those changes.
UNOS uses the following metrics for post-policy monitoring:

- Number and percent of registrations/candidates
- Waitlist mortality rates
- Number and percent of transplants
- Transplant rates
- Number and percent of donors/organs recovered
- Organ discard rates
- Actual vs. intended recipient
- Post-transplant outcomes (for example, patient and graft survival rates)
- Organ specific data points (KDPI, MELD, etc.)

These measures are also usually further categorized into sub-groups, such as donor characteristics, candidate/recipient characteristics, geography (such as OPTN region or DSA), and operational metrics.

Broader distribution will likely also require monitoring for allocation timing, the incidence of transplantable organs that are not recovered, late decline of organs resulting in reallocation and the accuracy of the use of potential transplant recipient (PTR) codes.

PTR codes in and of themselves represent an opportunity for improvement in data collection. The current PTR codes are overly broad and general and do not capture the specific reasons why an organ is

declined. If a transplant hospital declines an organ for operational reasons (timing, surgeon availability, program workload) then a transplant hospital may choose to enter a donor related PTR code so as not to be penalized or viewed as not having adequate resources to perform their duties. There needs to be a shift in this modality so that can capture accurate data and learn from experiences in broader distribution. The current PTR codes and system of evaluating these refusals does not incentivize the entry of accurate reasons for organ decline.

Data integrity and validity in this area are essential to the evaluation of policy and system changes.

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OPERATIONS AND SAFETY COMMITTEE TRANSPORTATION REPORT

Introduction:

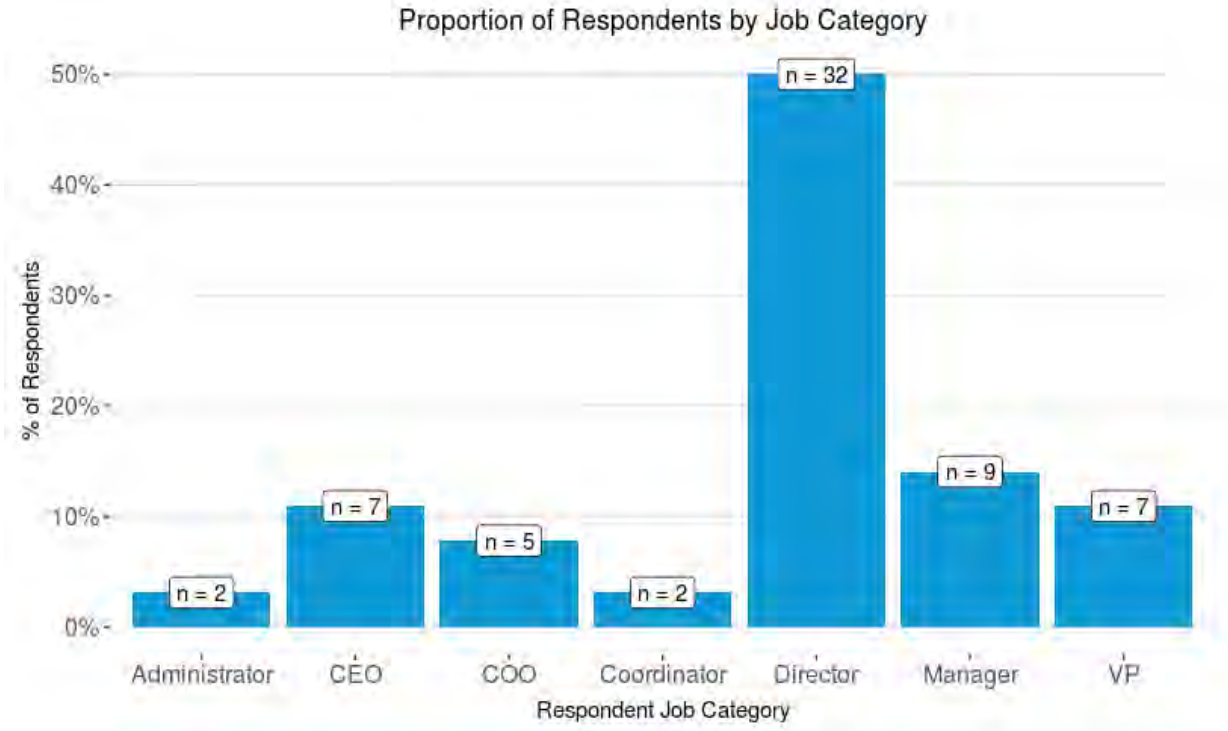
The OPTN/UNOS Operations and Safety Committee developed a questionnaire intended to assist the Ad Hoc Geography Committee and Organ-specific committees in their efforts to comply with the Department of Health and Human Services (HHS) directive[1] to eliminate DSA and Region as units of organ allocation. A major focus of the discussions regarding broader sharing is the likely increase in air travel that would be required if organs and surgical teams are travelling beyond "drivable" distances. To that end, our committee created a series of questions that focused on the operational aspects of broader sharing with a focus on ground and air travel logistics. Members of the committee then reached out to leadership in all 58 OPOs to determine the best individual(s) to answer the questions. For those OPOs that did not handle transportation for organ recovery, individual transplant centers were contacted to complete the questionnaire. The questionnaires were completed via a direct phone call with leadership of the OPO/Transplant Centers which allowed for both quantitative and qualitative data gathering. Once the questionnaires were completed, some of the questions were deemed "uninformative" by the committee and are not included in this document. Only those questions that the committee felt might be informative are included and focus on the issues that were included in the public comment proposal and some of the criteria used for SRTR modeling of allocation options (i.e. setting transition from driving to flying for liver at 200 nm). The full questionnaire is included in the appendix. Answers were analyzed nationally and by region as it was determined that significant regional variations in the answers to the questions was revealed.

Rationale for Study Questions:

1. Driving distance questions were included to determine the current state for decision making between when organ/team travel exceeded driving times/distances
2. Questions regarding requirements for teams vs organs flown were meant to determine if more local recovery efforts might influence needs for aircraft/pilots
3. Questions related to ability to find pilots/planes were included to determine if increasing the need for flying might delay donor recovery procedures thus increasing pre-donation hospital stays and/or increasing cold time in the event that delivery of organs is delayed due to pilot/plane availability

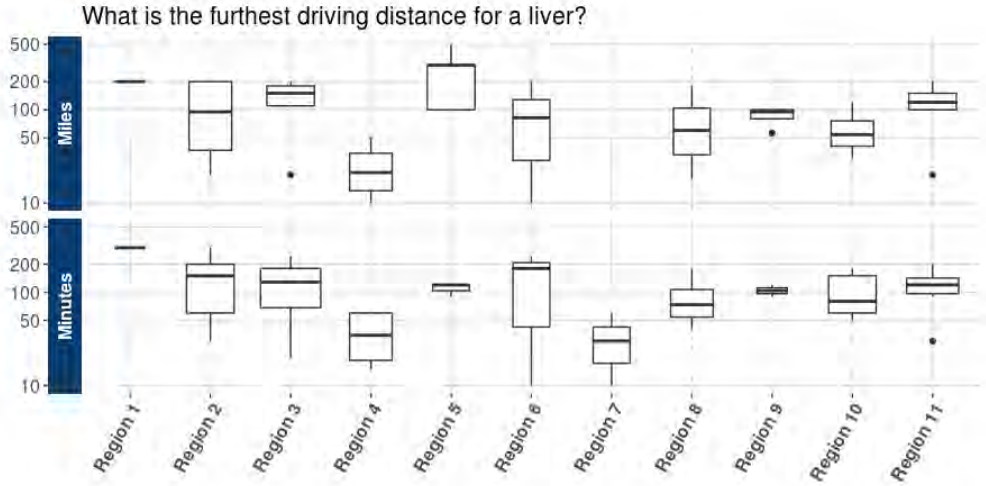
Contacts: Operations and Safety Committee members were able to complete questionnaires from 54 of the 58 OPOs and 10 transplant hospitals (where the transplant hospitals managed donor recovery transportation). The job roles of the respondents are depicted below:

[1] https://transplantpro.org/wp-content/uploads/sites/3/OPTN_letter_6.8.2018.pdf



Results:

Transition from driving to flying: Two hundred nautical miles was selected as the distance for modeling transition from driving to flying for liver allocation modeling. The graphic below supports the utilization of this distance.



*The box and whiskers represent the spread of responses. The thick middle line of the box represents the median. The ends of the box represent the IQR (25%-75% quantiles). The whiskers extend to 1.5 x IQR. Dots represent outliers (responses beyond the whiskers).

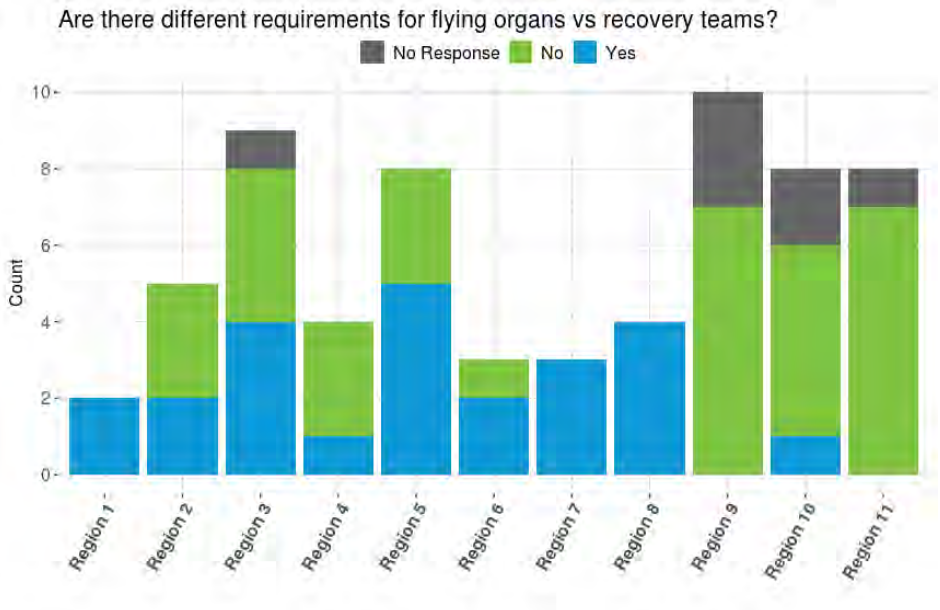
Selected comments from respondents:

- *"Highly dependent upon traffic conditions"*
- *Often determined by "time of day"*
- *"Weather and surgeon preference drive this cut-off"*
- *"More a time factor than mileage"*
- *"Nothing defined in policy….case by case basis"*
- *"Varies with organ"*

Equipment requirements for flying teams vs organs: The graphics below depict the number/percentage of respondents who indicated a difference between requirements for airplane type and pilot staffing between flying surgical teams vs organs. Nearly 40% (37.5%) of respondents indicated a difference. The answers differed by region.

Table 1. Are there different requirements for flying organs vs recovery teams?

	N	Percent
No	33	51.6%
Yes	24	37.5%
No Response	7	10.9%



Selected comments from respondents:

- *"Double pilots for people only, not organs"*
- *"Jets must have 2 pilots"*
- *"Always have 2 pilots when people on board, permit single pilot when only flying organs"*
- *"Prop is used to fly staff to cases. Jet is used for organs/surgeons"*
- *"Always 2 pilots and always a jet"*
- *"Single pilot for organs – always double pilots for moving people"*

Availability of Planes/Pilots: The availability of planes/pilots is depicted below. There are differences if recovery teams vs organs are flying and indicate that at times, planes may be available and pilots are not, and vice versa.

Table 2. Are you ever unable to find a plane/pilot for recovery team/organ?

Are you ever unable to find…	No	Yes	No Response
Pilot for recovery team?	40 (56.3%)	24 (33.8%)	7 (9.9%)
Pilot for organ?	47 (66.2%)	15 (21.1%)	9 (12.7%)
Plane for recovery team?	40 (56.3%)	25 (35.2%)	6 (8.5%)
Plane for organ?	48 (67.6%)	17 (23.9%)	6 (8.5%)

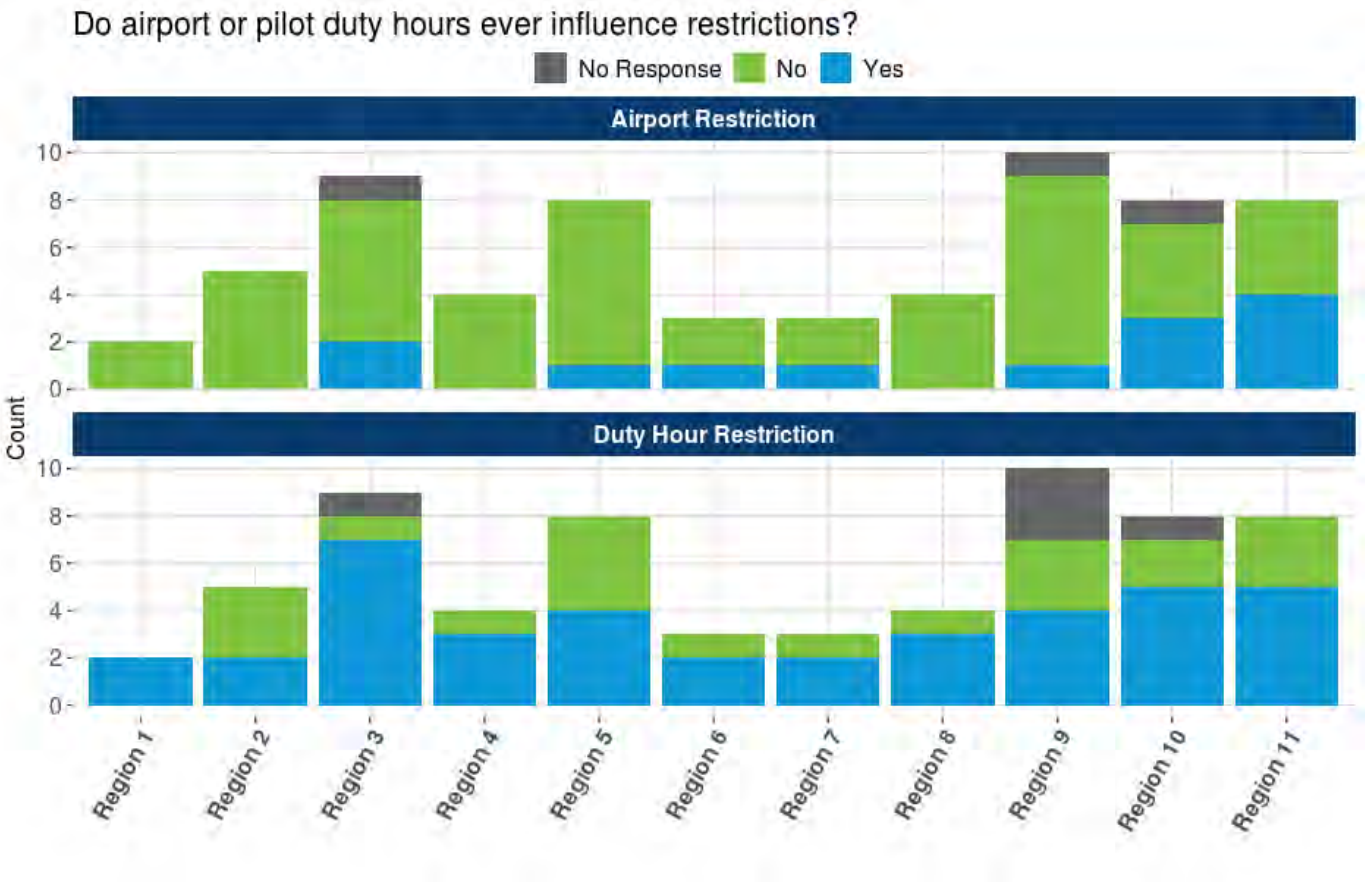
Selected comments from respondents:

- *"Rare, but charter company is expanding their fleet"*
- *"No planes/pilots are available on rare occasions"*
- *"Weather is always a factor. Large events in the state decrease the availability"*
- *"Always been able to find a plane but sometimes this causes delays"*
- *"Primarily during case reallocation with intra-op decline and time sensitive acceptance; several cases this year, at least one case this year when secondary charter choice at extreme expense for surgical team"*
- *"On rare occasions when a hospital plane not available, will charter"*
- *"Planes are ultimately located but there have been delays"*
- *"There has not been a time when we absolutely could not find a plane or team, but we have had delays"*
- *"Not unusual to delay OR for teams having trouble finding flight"*

Pilot duty hour restrictions: Pilot duty hour limitations are an additional variable that influences ability to fly organs/teams. OR delays could lead to need for additional teams to fly out to donor airports in the event that pilots time out.

Table 3. Do airport or pilot duty hour restrictions ever influence recovery?

	No	Yes	No Response
Airport restrictions	53 (74.6%)	14 (19.7%)	4 (5.6%)
Pilot duty hour restrictions	23 (32.4%)	42 (59.2%)	6 (8.5%)

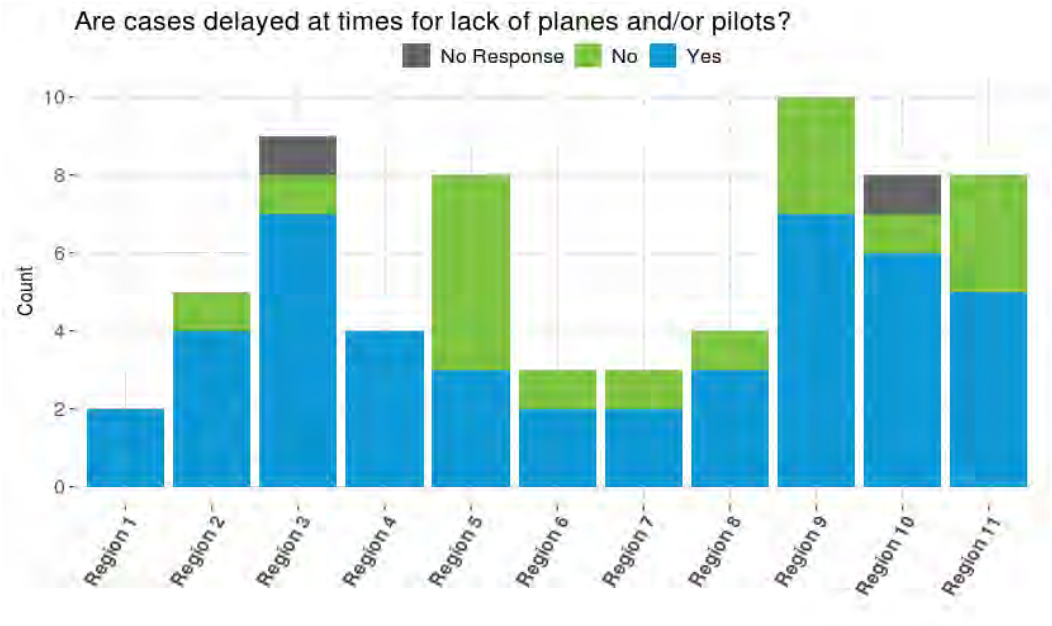


Selected comments from respondents:

- *"Pilot will "time out" if put on standby too soon or on the ground during organ recovery"*
- *Problems "due to pilot time restrictions"*
- *"…unable to distinguish source of unavailability (plane or pilot); may be pilot availability as rate limiting…pilot time out while on site has been an close call this year several times"*
- *"Sometimes need to delay the flight due to duty hours restrictions (relatively rare) or swap crews during procurement if duty hours are going to run out."*
- *"….pilots have timed out when flying very far - to the coasts to import organs…"*
- *"have had pilot time-out but not unable to find one"*
- *"pilots time out and sometimes needs another crew and one may not always be available"*

- *"Due to time out schedules of pilots, i.e. one pilot may time out in 2 hours, but the next pilot is not available for 5 hours"*
- *"…pilot timed out while waiting for recovery team-new pilots and plane had to be sent to recovery hospital to pick up team"*
- *"pilots/team times out frequently"*
- *"OR delay/bump resulted in pilot timing out....resulted in having to cancel recovery and delay 24hrs"*
- *"Seems to be happening more consistently"*
- *"never heard of this issue"*
- *"Case times adjusted due to pilot times"*
- *"If pilot availability or duty time is a concern we may strategically set the OR time based on those circumstances"*
- *"Can sometimes require additional plane when cases are delayed"*
- *"Experience a lot of time-out issues with pilots"*
- *"Typically because the recovery gets bumped due to trauma and pilots have to wait, gets bumped and have to fly in additional team"*
- *"definite impact on setting the OR time; safety concerns have led companies to be very strict about restriction"*
- *"Will flip teams when necessary and can add cost"*
- *Center "…has occasionally needed to secure a second plane/team when delays at donor site occurs or team times out"*
- *"Leads to delays in clamp times because pilot duty hours run out. NOT AN INSIGNIFANT PROBLEM! HAPPENS FREQUENTLY."*

Timing of donor OR times:



Selected comments from respondents:

- *"rarely, heart/lung teams will delay typically by 1-2hrs when planes take a while to find"*
- *"Prior to hiring broker in 2016, 45% of case were delayed due to flight arrangement problems"*
- *"Weather restrictions can be challenge"*
- *"The percent of cases delayed is very low"*
- *"Delays related to availability of surgeons (locally) and surgeons from outside teams (may be a surgeon or transportation issue)"*
- *"…Any time when aircraft are needed for use that are not our aircraft it takes additional time to get them into placed and can cause a delay. "*
- *"Need 5 hour heads up. Often leaves to delays. All charter companies need 5-6 hours of lead time. Some centers are demanding jets. Delays also occur because of lack of staff"*
- *"Usually, the delays are from teams to outside of the state. Especially heart and lung teams."*
- *"…when it is our donor, we can try to influence the timing of the cases in order to use our own plane…can go to OR sooner/later for weather. Also because we have our own plan we can get to donor hospitals faster and potentially get the unstable donor and utilize those organs"*
- *"Never had to turn down an organ but have had some delays"*
- *"Usually because Lung teams cannot find planes"*
- *"OR time regularly adjusted due to teams arriving from outside OPOs (OR start may not be delayed but more frequently setting of the OR time delayed based on flight availability)"*
- *"Delays are only due to surgical team availability"*
- *"Delays to start OR due to teams coming in"*
- *"…sometimes the delays are because the incoming team can't get a plane"*
- *"Delays in setting OR time. More often delays with last minute changes"*
- *"30% of cases experience some delay"*

Issues to Consider: Respondents conveyed that flying teams for organ recovery influences timing of the donor OR. Issues raised included:

1. Donor instability with longer pre-recovery times
2. Potential loss of organs due to logistics (e.g. lung)
3. Influence of case duration on OPO staffing requirements (inability to staff other cases if still managing existing cases due to time delays)
4. Concerns about pilot duty hours once activated if flight does not occur in timely fashion
5. Concerns about need for simultaneous fly-outs with broader sharing
6. Potential revocation of authorization with longer case times
7. Increased hospital costs related to longer case times
8. Airplane/pilot availability issues due to local sporting events or concerts where all private planes are committed to others
9. Pilot duty hour restrictions leading to need for additional pilots/planes to be flown into donor airports
10. Weather influence (need for strong local backup in the event of weather events that preclude flying)

Limitations: Obvious limitations to this report include the somewhat "anecdotal" nature of the questionnaire and the knowledge level of the respondents. We attempted to reach leadership at the OPOs and transplant centers as is indicated above in order to lessen these concerns.

Conclusions: The Operations and Safety Committee's goal in developing and executing this questionnaire was to assist the relevant UNOS/OPTN committees in their work towards eliminating DSAs and Region as units of allocation. We believe that the issues related to increased air travel and potential OR delays and costs are important issues for the committees to consider and hope that our work will help this process.