

Briefing Paper

Guidance on Effective Practices in Broader Distribution

OPTN Operations and Safety Committee

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Guidance on Effective Practices in Broader Distribution

Affected Policies: N/A
Sponsoring Committee: Operations and Safety
Public Comment Period: January 22, 2019 – March 22, 2019

Executive Summary

The OPTN 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 with the removal of DSA and Region as an allocation unit. 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 is intended to promote collaboration between OPOs, transplant hospitals, and histocompatibility labs, taking into consideration their needs and best practices.

What problem will this resource address?

Concerns about cost and transportation were raised during the 2015 Liver Forum¹ and continue to be a concern as noted by the numerous comments received during recent liver² and lung³ allocation public comment proposals. In response to proposed organ allocation policy changes that address broader distribution and the removal of donation service areas (DSAs) and regions as units of distribution, 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 UNOS 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 review of 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. As the elimination of DSAs and regions is expanded to other organs and result in an increase in travel and logistical challenges. The Committee was asked to provide recommendations 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 paper⁴ 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 considerations
- Data metrics

Was this proposal changed in response to public comment?

This proposal was initially on the consent agenda for the regional meetings. However, after receiving notice about concerns being expressed by the Association of Organ Procurement Organizations (AOPO), the determination was made to add the proposal to the discussion agenda for all the regional meetings. All eleven regions ultimately supported the proposal while providing similar comments regarding the inclusion of financial and billing information in the guidance document. **Figure 1** illustrates the support for the proposal at the regional meetings.

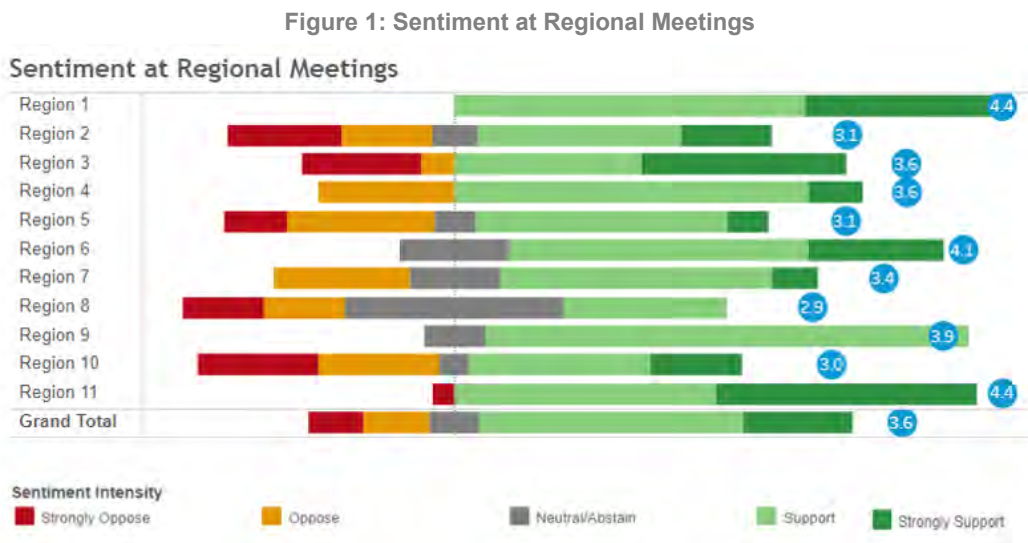


Figure 2 illustrates the sentiment by state for commenters on the proposal. The bar at the bottom of the figure is a representation of the average sentiment score for the proposal across each state. The score is calculated using a scale of 1-5. For example, a “strongly oppose” comment would receive a score of one, “oppose” would receive a two, “neutral/abstain” would receive a three, “support” would receive a four, and finally, a “strongly support” would receive a five.

Figure 2: Sentiment of Commenters by State

Effective Practices in Broader Organ Sharing

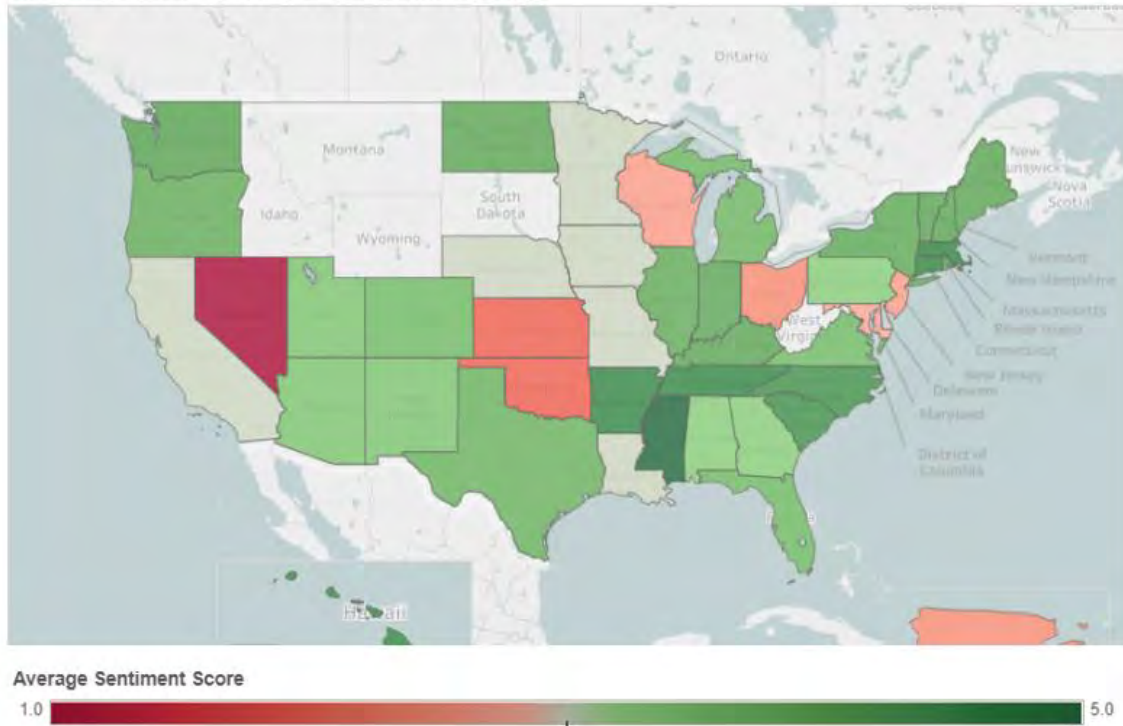
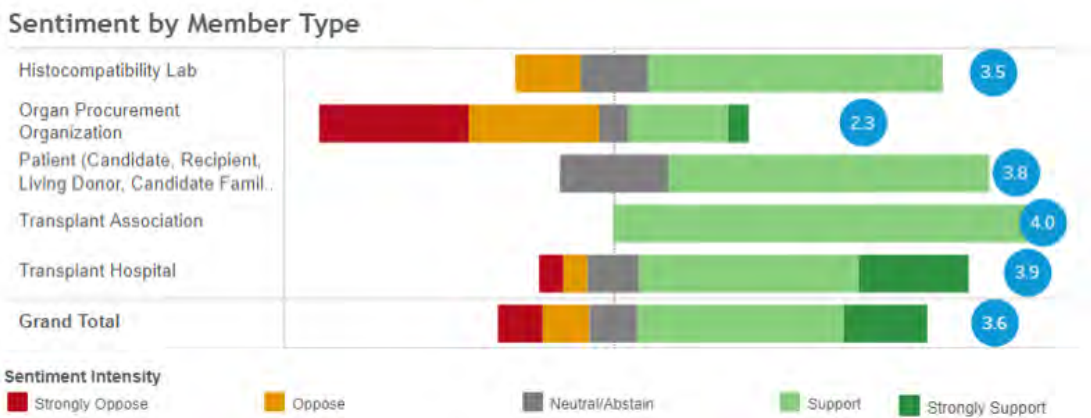


Figure 3 illustrates the sentiment based on member type with the scores calculated in the same way as Figure 2. The scores are similar across the member types with the exception of OPOs. The low score is attributed to the overall concern about the inclusion of financial and billing information in the guidance document.

Figure 3: Sentiment by Member Type



The regions, as well as the AOPO, opined that the financial and billing information falls outside the purview of the OPTN. Several OPTN Committees also reviewed the proposal, including the Ad Hoc Disease Transmission Advisory Committee, Organ Procurement Organization Committee, Transplant Administrators Committee, Transplant Coordinators Committee, and Liver and Intestinal Organ Transplantation Committee. All were supportive of the efforts of the Operations and Safety Committee to provide information on how members can adapt to the change toward broader organ distribution policies across all the organ systems. There were additional comments received regarding the overall organ procurement and allocation processes.

In addition to the concerns raised regarding the financial and billing sections of the guidance document, the American Society of Transplantation (AST) expressed concerns about the recommendation to rely more on virtual crossmatching and its potential conflict with OPTN policy. The Committee reviewed the current policy language and following discussions agreed that the guidance document does not recommend the increased use of virtual crossmatching in a way that conflicts with *OPTN Policy 4.6: Crossmatching*. The recommendation outlined in the guidance document is an effort to avoid the logistical challenges of shipping additional blood samples.

In response to the concerns raised about the financial and billing aspects of the guidance document, the Committee removed the following sections:

- Establishing Fair Market Value for Organ Procurement Activity
- Organ Procurement Malpractice Coverage Considerations
- Organ Procurement Related Billing

The Committee added the following language to the “Procurement Team Staffing Considerations” section:

“There are various practices and processes regarding how recovery surgeons are reimbursed for organ procurements amongst OPOs. Host OPOs should inform recovery teams of the applicable fee schedule, if any, as well as the processes for submitting invoices for recovery services.”

The Committee agreed that the intent of this section is to provide guidance for OPOs and transplant programs to be transparent and communicate about these practices as organs allocation policies move towards broader distribution. The AOPO President was consulted about the changes and agreed that the proposed changes to the document addresses the concerns raised by the organization.

The Committee reviewed and discussed the revisions made to the financial sections of the guidance document. There were concerns raised about whether the proposed modifications provided enough information to meet the intended purpose, which was to raise awareness about this issue. The Committee agreed that given the variation in practice across OPOs and the concerns raised during public comment, it is beyond the purview of the Committee and the OPTN to address financial issues. The Committee members did agree that it is important to state that there should be communication between OPOs and transplant surgeons about the process. During its March 28, 2019 meeting, the Committee agreed that the proposed revisions addressed the concerns from the community and unanimously approved the revised guidance document for submission to the Board of Directors.

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.

What are the potential costs associated with this resource?

Member

No estimated impact.

UNOS

Significant time is attributed to the Policy and Community Relations (PCR) department in the development of the paper in Committee, work to compose and modify the paper, and to respond to input from community stakeholders. Approximately 300 PCR hours is estimated in development and implementation. Professional Education plans to produce a small instructional effort to aid in sharing the guidance with the community.

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, the Committee did request feedback from the community on additional data elements that could be collected to better evaluate the impact of broader distribution. There was limited feedback about recommended data points but support for collecting additional data to better inform future broader distribution proposals. The Committee will develop a separate proposal to address this data collection in time for the next public comment period that starts in August 2019.

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 report⁵ 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 hires⁶."

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/>

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

53
54 **Streamlining Communications and Information Distribution**

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

59
60 DonorNet® has proved a valuable tool in the allocation process. Since the implementation of electronic
61 notifications of organ offers through DonorNet, OPOs and transplant hospitals have had the ability to
62 share and review donor information in a centralized location and reduced the amount of donor data
63 shared verbally. Organ allocation became more efficient as a result, and now DonorNet serves as an
64 integral tool in the organ donation process. Still, enhancements are needed and become more essential
65 as organs are distributed across DSAs more frequently.

66
67 In 2018, operating room (OR) timing was added as a feature to DonorNet (**Figure 1** “Follow Donor”). This
68 enabled OPOs to enter the anticipated OR timing and transplant hospitals to receive updates of that
69 information electronically. Though this was added at the request of DonorNet users, it has not been
70 widely utilized. Similar features should be added to DonorNet that enable the electronic sharing of donor
71 information such as updated clinical data, crossclamp time, recovery times and donation after circulatory
72 death (DCD) related data. Such an update would enable transplant hospitals to be aware of case
73 progress real-time.

74
75 **Figure 1: DonorNet “Follow the Donor” Feature**



The screenshot shows a user interface for the 'Follow the Donor' feature. It includes two rows of radio button options. The first row is labeled 'OR Date:' and has three options: 'Not Set', 'Tentative', and 'Scheduled'. The second row is labeled 'Recovery Facility:' and has two options: 'Donor Hospital' and 'Alternate Facility'. To the right of these options are two buttons: 'Follow Donor' and 'Send Alert'. The 'Follow Donor' button is orange, and the 'Send Alert' button is grey.

76
77 The benefits of transplant hospitals seeing images of organs or diagnostic studies are obvious. These
78 capabilities should be utilized as frequently as possible to enable key decision makers to make the best
79 assessment possible of the suitability of organs being offered for their transplant candidates. Many OPOs
80 are already utilizing third party file sharing platforms to share donor cardiac catheterizations, chest and
81 abdominal computerized tomography (CTs), bronchoscopies, echocardiograms or other video image files
82 to better enable optimal evaluation of organ function, size and suitability by transplant centers.

83
84 In 2012, members of multiple OPTN committees put forth a guidance document to promote effective
85 practices for the photography and sharing of organ photos or biopsy images. This guide is available on
86 the OPTN website at this address:
87 https://optn.transplant.hrsa.gov/media/1265/donor_liver_resources_201206.pdf

88
89 The Committee recommends DonorNet enhancements that will enable a consistent process for the
90 sharing of post-recovery donor test results from OPOs to transplant hospitals. This could include
91 information as standard blood, sputum and urine cultures, pathology results, or additional infectious
92 disease testing that may have been performed. Currently, there is variability of how post-recovery donor
93 test results are shared from OPOs to transplant center Patient Safety Contacts.

94
95 **Histocompatibility Considerations with Broader Geographic Organ Distribution**

96 The following guiding principles will be important for OPOs:

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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.

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

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121
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 UNetsm 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.

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

128
129 More information on pre-transplant crossmatch requirements can be found at
130 <https://transplantpro.org/news/labs/policy-clarification-pre-transplant-crossmatch-requirements/>

131
132 **Organ Allocation Procedures**

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

141
142 OPOs should employ a donor data validation step to ensure that accurate donor information is entered
143 into DonorNet at the time of running the match runs to ensure that the appropriate candidates appear on
144 the list. UNOS performs such a validation process each time the Organ Center receives a request to offer
145 organs from the Organ Center. That experience suggests about 3 in 100 matches are found to have a
146 discrepancy that may impact a match.

147

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

152
153 Once initiating organ allocation, OPOs should make efforts to place each organ with a primary and a
154 back-up candidate. Recently introduced OPTN policy⁷ has modified the time frame that transplant centers
155 have to evaluate organ offers. From the time of notification, transplant centers have 1 hour to review the
156 donor information and enter a response as either a provisional yes or refusal. Transplant centers should
157 make an effort to respond not just for the candidate for whom they are receiving the offer but also those
158 candidates further down the match run at their center. This will help streamline the allocation process by
159 reducing unnecessary electronic notifications. This will also enable OPOs to know for which candidates a
160 transplant center may have interest even if they are declining the organ for their top candidate(s).

161
162 *Policy 5.4.D: Backup Organ Offers* states that “OPOs may make backup offers for all organs. Transplant
163 programs must treat backup offers the same as actual organ offers and must respond within one hour of
164 receiving the required deceased donor information for an organ. If a transplant program refuses to
165 consider or does not respond to a backup offer, the offer will be considered refused.” It is strongly
166 encouraged that transplant hospitals should seriously consider back-up organ offers with the anticipation
167 that the organ offer may become a primary offer. Since the implementation of DonorNet and electronic
168 organ offer notifications, the “Provisional Yes”, at times, may have devolved into a placeholder when the
169 offer is for a backup candidate. Frequently an OPO may have an organ allocated to both a primary and
170 backup hospital only to later have the primary hospital decline for recipient-related reasons and the
171 backup hospital, now primary, decline the offer due to information that had been known since they had
172 entered the “Provisional Yes.” This practice can have significant consequences in delaying organ
173 placement and impact the transplantation of suitable organs.

174
175 The placement of one organ often impacts the placement of all other organs from that donor, including
176 the placement of multi-organ combinations such as kidney-pancreas, heart/lung or extra-renal organs
177 with a kidney. Since multiple organ allocation occurs on a primary organ match run, transplant centers
178 being offered the other organs following the sequence of other match runs may not be aware of the
179 multiple organ allocation. For example, if a liver is placed with a liver candidate who also requires a
180 kidney, the transplant hospitals being offered the kidneys by way of the kidney match run may not see
181 that the liver candidate also requires a kidney. A kidney center may perceive their candidate as primary
182 for one of the kidneys. Communication and transparency of the allocation plan to transplant centers being
183 offered organs is essential. Many have suggested that the plan and updates regarding allocation be typed
184 into the “Highlights” section of DonorNet so that transplant hospitals are aware of their status in the
185 allocation.

186
187 **Recognizing Seasonal and Geographic Endemic Infection in Organ Donors**

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

199

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

200 **Establishing the Time of Organ Recovery**

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

- 205
- 206 • Evaluate and consider the organs being offered
- 207 • Request additional donor evaluative procedures deemed necessary for an appropriate decision
- 208 • Mobilize necessary resources within the transplant hospital
- 209 • Enable crossmatching as needed for the intended candidate
- 210 • Allow for the logistical needs of the recovery and transport to the donor hospital
- 211 • Safely bring in the intended candidates for the transplant procedure

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

217
 218 Providing transplant hospitals adequate time to enable organ acceptance with surgical recovery being the
 219 goal, the needs of all programs involved may at times result in a transplant hospital having to expedite
 220 their processes. The OR time should be set based on the needs of other surgical teams and their
 221 candidates, availability of OPO resources, donor hospital resources or donor family time constraints.

222
 223 Unnecessary delays to perform organ recoveries can have negative consequences that impact organ
 224 donation in many ways. Prolonged time in the donor hospital ICU can impact the donor hospital staff's
 225 perception of the organ donation process and their support of organ donation in their institutions.
 226 Prolonged time in the donor hospital ICU ties up resources that may be available to other critically ill
 227 patients at that hospital. Extended time prior to procurement, even with the support of the donor family,
 228 can have negative emotional impact on the donor family members and loved ones. Unnecessary delays
 229 to complete the organ recovery in a timely manner can have an impact on OPO staffing which has a
 230 trickle-down effect on other donor activity in an OPO service area. Donor stability during hemodynamic
 231 management for extended periods of time can result in unexpected donor cardiac arrest resulting in a
 232 loss of transplantable organs.

233
 234 *Policy 2.14.G: Start Time for Organ Procurement* states "After organs have been offered and accepted,
 235 recovery teams must agree on the time the procurement will begin. If they cannot agree on the start time
 236 for the procurement, the host OPO has the authority to withdraw the offer from the transplant hospital that
 237 cannot agree on the start time for procurement."

238 **Organ Procurement Surgeon Models**

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

- 243
- 244 • Use of Employed Surgeons
- 245 • Use of Affiliated Surgeons
- 246 • Non-Employed/Non-Affiliated

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

253
254 *Affiliated surgeons* are not directly employed by the transplant hospital or organ procurement organization
255 but contracted to provide surgical services. This model can be equally successful if alignment language is
256 clear and the relationship is mutually beneficial to the surgeon and transplant hospital. Considerations for
257 administrative-related compensation should be evaluated to ensure that an affiliated surgeon is involved
258 with the quality management and other operational discussion.

259
260 Many transplant centers and organ procurement agencies also informally utilize surgeons that are *Non-*
261 *Employed/Non-Affiliated* to augment their procurement-related staffing needs. This type of arrangement is
262 often based on trust and collegial relationships between surgeons. There is often no formal contract
263 between procuring surgeon and transplant center, and this can lead to a myriad of challenges that should
264 be evaluated closely. Compensation issues related to organ recovery attempts though they may not
265 actually result in organ procurement should be discussed in advance of any recovery. The skills required
266 to assess an organ are as equally important as the surgical technique and experience. Organ recovery
267 requires experience, skill, and insights; therefore, surgeons should be compensated for their time and
268 expertise regardless of the ultimate utilization of the organ.

269 **Procurement Team Staffing Considerations**

271 Transplant hospitals and OPOs should assess their capabilities with respect to the support of the organ
272 recovery process. With increased geographic distribution, it is expected that organ recovery teams may
273 be susceptible to greater risk of burn-out and fatigue.

274
275 Due to increased air transport of organ procurement teams (OPO staff and surgeons) to perform organ
276 recoveries it is recommended that whenever possible travel of personnel is limited. Transplant hospitals
277 may wish to rely on a local organ recovery surgeon to assess and procure organs on their behalf. It is
278 recommended that transplant hospitals identify surgeon colleagues in neighboring regions that they may
279 trust to perform these recoveries and reduce their air travel.

280
281 OPOs that provide procurement coordinators/preservationists to accompany recovery surgeons for
282 procurements in neighboring regions may wish instead to request and rely on the perfusion services of
283 the host OPO. With increased geographic distribution, the frequency of these events will increase
284 significantly and OPOs should, when possible, seek the assistance of neighboring OPOs to provide these
285 services rather than increase the number of staff traveling for the recovery to perform tasks that could be
286 performed by the host OPO staff.

287
288 There are various practices and processes regarding how recovery surgeons are reimbursed for organ
289 procurements amongst OPOs. Host OPOs should inform recovery teams of the applicable fee schedule, if
290 any, as well as the processes for submitting invoices for recovery services.

291 **Data Metrics**

293 Following the implementation of any major change in policy, such as the broader geographic distribution
294 of organs, there is always the need to monitor the effects of those changes.

295 The OPTN uses the following metrics for post-policy monitoring:

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

305 These measures are also usually further categorized into sub-groups, such as donor characteristics,
306 candidate/recipient characteristics, geography (such as OPTN region or DSA), and operational metrics.
307

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

311
312 PTR codes in and of themselves represent an opportunity for improvement in data collection. The current
313 PTR codes are overly broad and general and do not capture the specific reasons why an organ is
314 declined. If a transplant hospital declines an organ for operational reasons (timing, surgeon availability,
315 program workload) then a transplant hospital may choose to enter a donor related PTR code so as not to
316 be penalized or viewed as not having adequate resources to perform their duties. There needs to be a
317 shift in this modality so that can capture accurate data and learn from experiences in broader distribution.
318 The current PTR codes and system of evaluating these refusals does not incentivize the entry of accurate
319 reasons for organ decline.

320
321 Data integrity and validity in this area are essential to the evaluation of policy and system changes.
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325 **OPERATIONS AND SAFETY COMMITTEE TRANSPORTATION REPORT**
326

327 **Introduction:**
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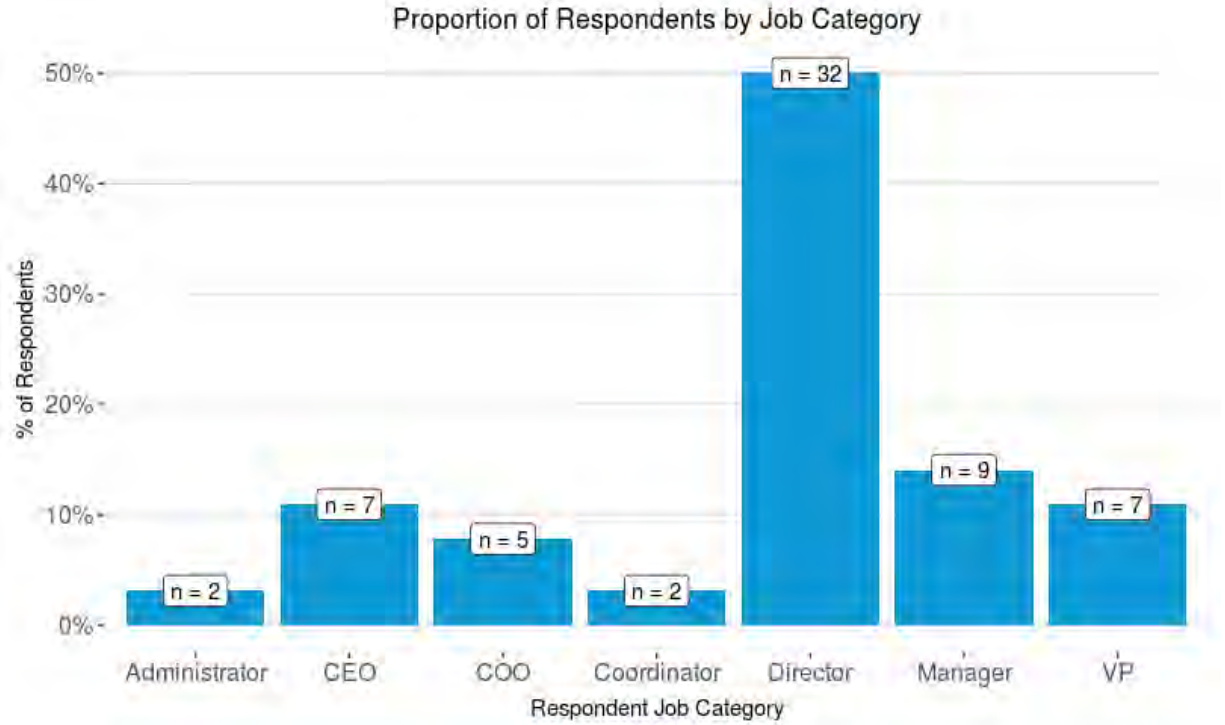
329 The OPTN Operations and Safety Committee developed a questionnaire intended to assist the
330 Ad Hoc Geography Committee and Organ-specific committees in their efforts to comply with the
331 Department of Health and Human Services (HHS) directive⁸ to eliminate DSA and Region as
332 units of organ allocation. A major focus of the discussions regarding broader sharing is the likely
333 increase in air travel that would be required if organs and surgical teams are travelling beyond
334 “drivable” distances. To that end, our committee created a series of questions that focused on
335 the operational aspects of broader sharing with a focus on ground and air travel logistics.
336 Members of the committee then reached out to leadership in all 58 OPOs to determine the best
337 individual(s) to answer the questions. For those OPOs that did not handle transportation for organ
338 recovery, individual transplant centers were contacted to complete the questionnaire. The
339 questionnaires were completed via a direct phone call with leadership of the OPO/Transplant
340 Centers which allowed for both quantitative and qualitative data gathering. Once the
341 questionnaires were completed, some of the questions were deemed “uninformative” by the
342 committee and are not included in this document. Only those questions that the committee felt
343 might be informative are included and focus on the issues that were included in the public
344 comment proposal and some of the criteria used for SRTR modeling of allocation options (i.e.
345 setting transition from driving to flying for liver at 200 nm). Answers were analyzed nationally and
346 by region as it was determined that significant regional variations in the answers to the questions
347 was revealed.
348

349 **Rationale for Study Questions:**

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

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

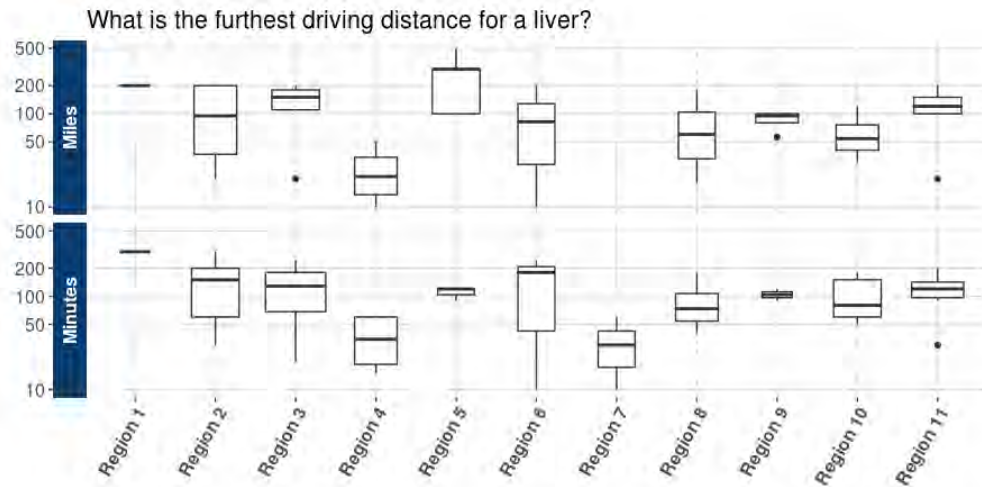
⁸ https://transplantpro.org/wp-content/uploads/sites/3/OPTN_letter_6.8.2018.pdf



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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).

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Selected comments from respondents:

- *“Highly dependent upon traffic conditions”*
- *“Often determined by “time of day”*
- *“Weather and surgeon preference drive this cut-off”*

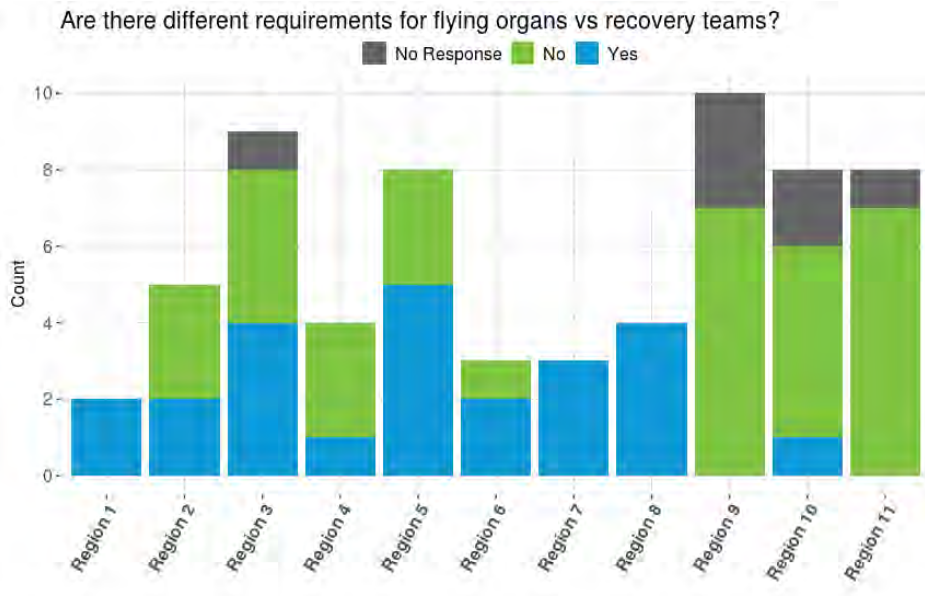
- 376 • “More a time factor than mileage”
- 377 • “Nothing defined in policy....case by case basis”
- 378 • “Varies with organ”

379 **Equipment requirements for flying teams vs organs:** The graphics below depict the
 380 number/percentage of respondents who indicated a difference between requirements for airplane
 381 type and pilot staffing between flying surgical teams vs organs. Nearly 40% (37.5%) of
 382 respondents indicated a difference. The answers differed by region.
 383
 384

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%

385



386

387

388 **Selected comments from respondents:**

- 389 • “Double pilots for people only, not organs”
- 390 • “Jets must have 2 pilots”
- 391 • “Always have 2 pilots when people on board, permit single pilot when only flying organs”
- 392 • “Prop is used to fly staff to cases. Jet is used for organs/surgeons”
- 393 • “Always 2 pilots and always a jet”
- 394 • “Single pilot for organs – always double pilots for moving people”

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

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415**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"

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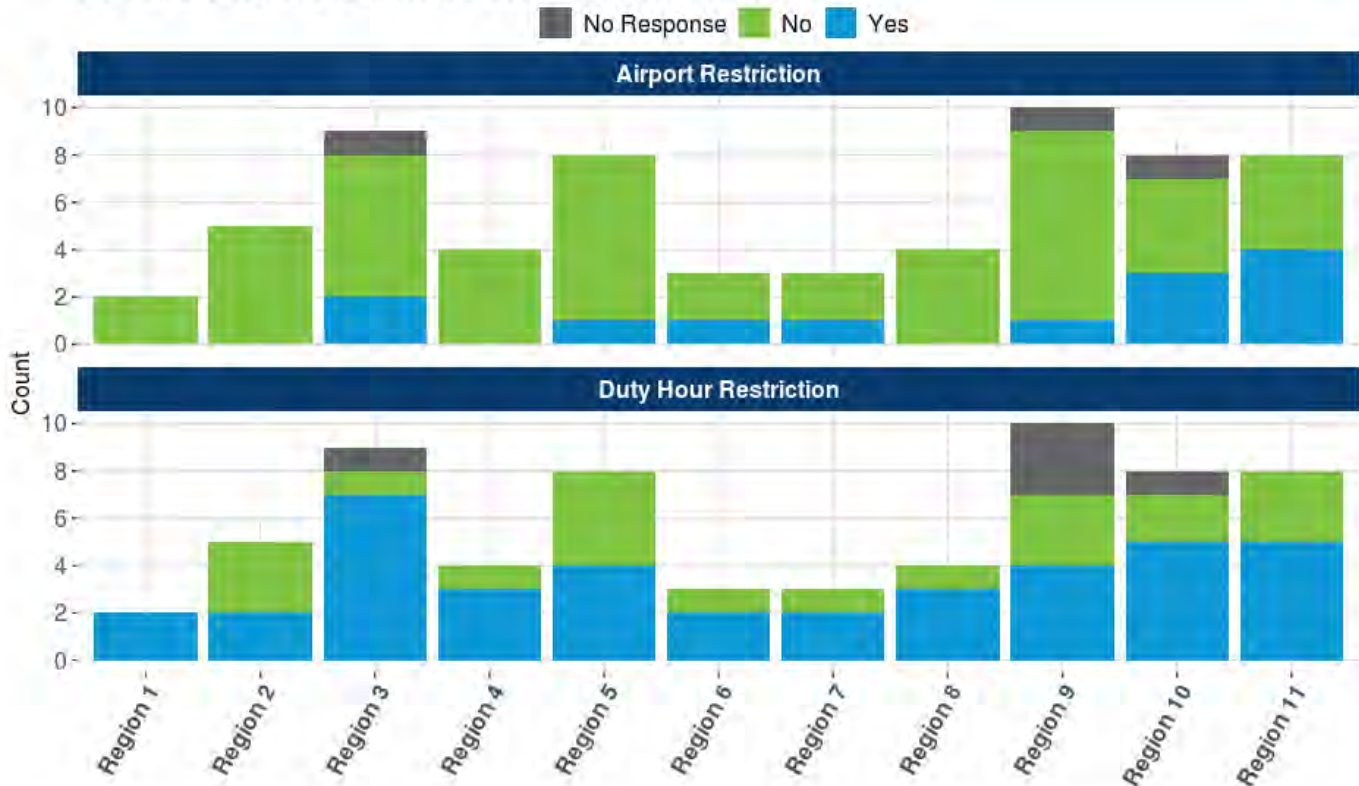
Pilot duty hour restrictions: Pilot duty hour limitations are an additional variable that influences ability to fly organs/teams. OR delays could lead to need for additional teams to fly out to donor airports in the event that pilots time out.

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%)

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Do airport or pilot duty hours ever influence restrictions?



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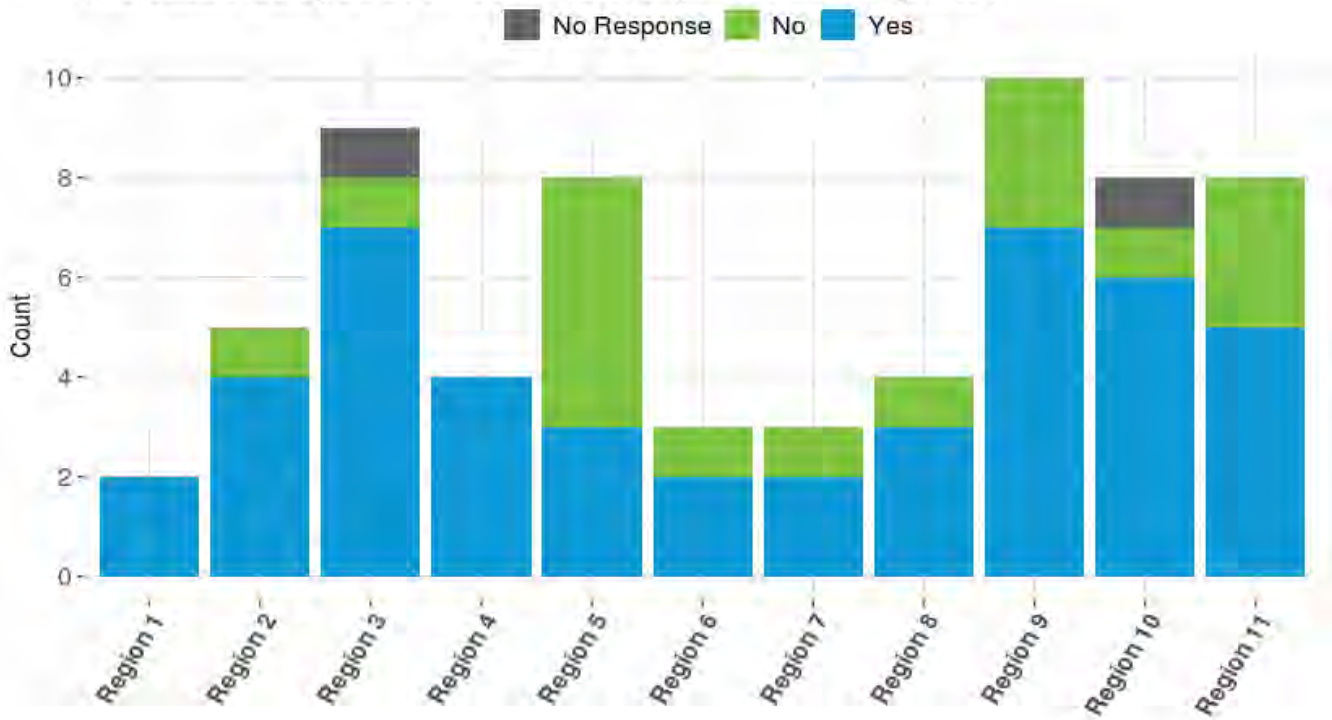
Selected comments from respondents:

- *“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”*

- 448 • “Can sometimes require additional plane when cases are delayed”
- 449 • “Experience a lot of time-out issues with pilots”
- 450 • “Typically because the recovery gets bumped due to trauma and pilots have to wait, gets
- 451 bumped and have to fly in additional team”
- 452 • “definite impact on setting the OR time; safety concerns have led companies to be very strict
- 453 about restriction”
- 454 • “Will flip teams when necessary and can add cost”
- 455 • Center “...has occasionally needed to secure a second plane/team when delays at donor site
- 456 occurs or team times out”
- 457 • “Leads to delays in clamp times because pilot duty hours run out. NOT AN INSIGNIFANT
- 458 PROBLEM! HAPPENS FREQUENTLY.”

459 Timing of donor OR times:
460

Are cases delayed at times for lack of planes and/or pilots?



462 Selected comments from respondents:

- 463
- 464 • “rarely, heart/lung teams will delay typically by 1-2hrs when planes take a while to find”
- 465 • “Prior to hiring broker in 2016, 45% of case were delayed due to flight arrangement problems”
- 466 • “Weather restrictions can be challenge”
- 467 • “The percent of cases delayed is very low”
- 468 • “Delays related to availability of surgeons (locally) and surgeons from outside teams (may be
- 469 a surgeon or transportation issue)”
- 470 • “...Any time when aircraft are needed for use that are not our aircraft it takes additional time
- 471 to get them into placed and can cause a delay. “
- 472 • “Need 5 hour heads up. Often leaves to delays. All charter companies need 5-6 hours of
- 473 lead time. Some centers are demanding jets. Delays also occur because of lack of staff”
- 474 • “Usually, the delays are from teams to outside of the state. Especially heart and lung teams.”

- 475 • "...when it is our donor, we can try to influence the timing of the cases in order to use our own
476 plane...can go to OR sooner/later for weather. Also because we have our own plan we can
477 get to donor hospitals faster and potentially get the unstable donor and utilize those organs"
478 • "Never had to turn down an organ but have had some delays"
479 • "Usually because Lung teams cannot find planes"
480 • "OR time regularly adjusted due to teams arriving from outside OPOs (OR start may not be
481 delayed but more frequently setting of the OR time delayed based on flight availability)"
482 • "Delays are only due to surgical team availability"
483 • "Delays to start OR due to teams coming in"
484 • "...sometimes the delays are because the incoming team can't get a plane"
485 • "Delays in setting OR time. More often delays with last minute changes"
486 • "30% of cases experience some delay"

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

- 489
- 490 1. Donor instability with longer pre-recovery times
 - 491 2. Potential loss of organs due to logistics (e.g. lung)
 - 492 3. Influence of case duration on OPO staffing requirements (inability to staff other cases if
493 still managing existing cases due to time delays)
 - 494 4. Concerns about pilot duty hours once activated if flight does not occur in timely fashion
 - 495 5. Concerns about need for simultaneous fly-outs with broader sharing
 - 496 6. Potential revocation of authorization with longer case times
 - 497 7. Increased hospital costs related to longer case times
 - 498 8. Airplane/pilot availability issues due to local sporting events or concerts where all private
499 planes are committed to others
 - 500 9. Pilot duty hour restrictions leading to need for additional pilots/planes to be flown into
501 donor airports
 - 502 10. Weather influence (need for strong local backup in the event of weather events that
503 preclude flying)

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

507

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

RESOLUTION 1

At a meeting of the OPTN Board of Directors convened on Month, days, year in City, State, the following resolution is offered.

A resolution to...

Sponsoring Committee: Operations and Safety

Public Comment

Committee: X in favor as amended or with comments, X had no comment or did not vote

Region: X in favor, X opposed

Individual: X responses

RAIS:

Project size: Very large

Implementation estimate: x hours

Annual maintenance estimate: x hours

Requires/Does not require additional programming in UNetsm.

RESOLVED, that the guidance document/white paper entitled “”, as set forth below, is hereby approved, effective pending implementation and notice to OPTN members or Month/Day/Year.

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Resource

NOTE: Policy Editor will pull in final resource from the section above, review and format as necessary, and correctly number the resolution when we create the Board Book.

#