UNITED NETWORK FOR ORGAN SHARING

Attachment A
UNOS Responses to February 10, 2020 Letter

1. How does UNOS fulfill the requirements of 42 C.F.R §121.10(b), which tasks the OPTN with monitoring and overseeing all OPOs?

The OPTN maintains a robust system for monitoring OPTN member compliance with "OPTN Obligations."[1] OPTN Obligations are defined in OPTN Bylaw: "OPTN obligations include all the applicable provisions of the National Organ Transplant Act (NOTA), OPTN Final Rule, OPTN Charter, OPTN Bylaws, and OPTN Policies."[2] Pursuant to 42 C.F.R. §121.10(b), the OPTN conducts ongoing and periodic reviews of each member OPO for compliance with OPTN Obligations, including the OPTN Final Rule and OPTN Policies. As members of the OPTN, OPOs are obligated to adhere to OPTN Obligations, and are subject to the OPTN's monitoring processes.

The OPTN Final Rule defines the scope of the OPTN's role in monitoring OPOs; it does not assign the OPTN the duty of monitoring OPO compliance with all OPO statutory and regulatory requirements that exist externally to the OPTN, such as compliance with CMS regulations or financial reporting requirements.

The OPTN employs a number of different strategies for monitoring members, including routine reviews[3], performance reviews,[4] and non-routine compliance reviews in response to specific incidents.

a. How does UNOS currently fulfill its requirement for ongoing monitoring and periodic reviews of OPOs for underperformance and what triggers or performance measures are used by UNOS to define OPO underperformance?

The OPTN Member Monitoring Process document details the specific ways in which OPTN members are monitored for compliance with OPTN Obligations. The OPTN specifically monitors OPOs through desk reviews[5], routine site surveys[6], allocation reviews,[7] and for performance, which are each described in detail in the accompanying Folder 1.

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[1] "OPTN Member Monitoring Processes." https://optn.transplant.hrsa.gov/media/2937/optn_member_monitoring_processes.pdf (Accessed on Feb. 19, 2020). Provided in Folder 1.
[2] OPTN Bylaws at Page 202 and *passim*. Available at: https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf
[3] "OPTN Member Evaluation Plan." https://optn.transplant.hrsa.gov/media/1202/evaluation_plan.pdf (Accessed on Feb. 19, 2020). Provided in Folder 1.
[4] "What to Expect: Performance Reviews." https://optn.transplant.hrsa.gov/media/2939/what_to_expect_performance_reviews.pdf (Accessed on February 19, 2020). Provided in Folder 1.
[5] *See* OPTN Member Monitoring Processes at 8.
[6] *Id.* at 7.
[7] *Id.* at 6.

The OPTN reviews OPO aggregate organ yield, as well as kidney, liver, heart, and lung yield, on an ongoing basis. To assist the OPTN in identifying OPOs for review, the Scientific Registry of Transplant Recipients (SRTR) creates reports twice a year using a statistically driven method that includes risk adjustment for the makeup of an OPO's donor population. Each report includes donors over a 24-month period, with an approximately six-month delay between the end of the report period and the time the report is generated. Each time the reports are generated, the reporting period moves forward six months. The MPSC identifies OPOs for review according to the criteria outlined in Appendix B.2: OPO Performance Requirements of the OPTN Bylaws, which states:

> The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area or OPO in question. Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.
>
> The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:
>
> 1. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10).
> 2. A ratio of observed to expected yield less than 0.90.
> 3. A two-sided p-value is less than 0.05.
>
> All three criteria must be met for an OPO to be identified for MPSC review.[8]

Performance Analysis staff from UNOS send each OPO identified for review a questionnaire to complete. The questionnaire allows the OPO to provide information about its operations and donors during the review period. The OPO also receives a donor yield spreadsheet that lists select donors from whom the organ(s) for which the OPO was identified was not transplanted. The OPO must provide information on the placement efforts, factors affecting placement, and organ details for the identified donors; it may also provide information about opportunities identified and steps taken to improve organ yield.

Once an OPO returns its questionnaire and supporting documentation to the OPTN, a performance analyst reviews the submission to verify that all of the requested documents have been submitted. When the member's submission is determined to be complete, the information is prepared for MPSC review. The MPSC's approach is further detailed in the Bylaws:

> If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a

[8] OPTN Bylaws, Appendix B.2: OPO Performance Requirements.

> noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix L: Reviews and Actions*.
> As part of this process, the MPSC may conduct a peer visit to the OPO at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to Appendix L: Reviews and Actions.[9]

i. What, if any, efforts has UNOS undertaken to ensure the accuracy and consistency of OPO outcome measure data?

We can answer this question with regard to how UNOS ensures the accuracy and consistency of data reported to and maintained by the OPTN. We do not have information on the extent to which those data are used by CMS in the OPO outcome measure calculation, or what measures CMS takes to ensure the accuracy of those data or any other data CMS uses to calculate OPO outcome measures.

The accuracy, quality, and integrity of OPTN data is of utmost importance to us. UNOS has developed standards for any entity that provides data or information to our system. First, OPTN policy requires members to submit accurate data to the OPTN, and holds that "[m]embers are responsible for providing documentation upon request to verify the accuracy of all data submitted to the OPTN through the use of standardized forms."[10] Additionally, every individual that uses a UNOS System, which includes UNet, our suite of applications supporting the transplantation system, agrees to the UNOS Terms of Use, which includes the following provision:

> **Data Accuracy**: You represent and warrant that the data entered by you or your authorized personnel in UNOS Systems are accurate, timely, and complete to the best of your knowledge, information and belief; and that these data are based upon information contained in corresponding medical records and other source documents, or where appropriate, are based upon clinical observation.

During routine OPO site surveys, site surveyors review rates of compliance with submission dates for the Deceased Donor Registration (DDR) form, the Deceased Donor Feedback form, and Potential Transplant Recipient (PTR) refusal codes. Site surveyors also review a sample of deceased donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet on the DDR is consistent with source documentation.[11] Additionally, site surveyors review a sample of deceased donor records for documentation regarding authorization to donate, reasons for excluding any donors from the eligible death definition, and declaration of death notes.

ii. Does UNOS ever audit self-reported data submitted by OPOs in relation to measures under 42 C.F.R. § 486.318(a) and (b)? If so, please detail how frequently such audits occur and what action is taken in response to an OPO that is found to have submitted inaccurate data.

[9] *Id.*
[10] OPTN Policy 18.1: Data Submission Requirements.
[11] OPTN Member Evaluation Plan.

Yes. In the previous answer, we explained how we ensure the accuracy of data reported to the OPTN. To the extent that OPTN data are used by CMS in the OPO outcome measure calculation, or what measures CMS takes to ensure the accuracy of those data or any other data CMS uses to calculate OPO outcome measures, we do not have information.

iii. Has UNOS provided guidance to OPOs on the definition of "eligible deaths" for reporting the number of organs recovered per eligible death?

Yes. OPTN policy includes a definition of "eligible death,"[12] the current version of which has been in place since the OPTN adopted amendments to align the OPTN data collection with the CMS definition on January 1, 2017. This definition is also included in Help Documentation in the OPO application of our UNet System: DonorNet. Prior to the implementation, UNOS provided education, available to all members, in a module called "Modifications to the Imminent and Eligible Neurological Death Data Reporting Definitions."

b. What, if any, steps has UNOS taken in response to media reports about staffing shortages at selected OPOs?

The OPTN Bylaws require that "[e]ach OPO must have the necessary staff to recover and distribute organs according to OPTN obligations, including an administrative director, a medical director, an organ donation coordinator, and an organ procurement specialist."[13] OPOs must submit written notice immediately (and within 30 days) after learning that the OPO administrative director or medical director plans to leave or otherwise change positions and no longer serve in one of these roles, and must notify UNOS if it has not filled a vacant administrative or medical director position permanently within six months. We investigate compliance with this Bylaw further when an OPO fails to inform UNOS of a change in key personnel within 30 days of departure, or fails to submit the replacement's information no less than 30 days before the change will take effect.[14]

If UNOS learns of an OPO's failure to adhere to its OPTN obligations, such as reporting a key personnel change as described above, or any other staffing shortages that raise concerns about whether the OPO has "necessary staff to recover and distribute organs according to OPTN obligations," or if the OPO's staffing poses a potential threat to patient health or public safety, UNOS will initiate a patient safety/non-routine compliance review.

First, UNOS Safety Analysts review and triage reports to determine whether:

- Readily available information suggests the report is accurate
- The potential incident meets any of the criteria requiring it to be reported to HRSA according to the OPTN contract
- The potential incident involves issues such as actual, or the potential for, direct harm to patients, a risk to patient health or public safety, or a risk to the integrity of the OPTN

If the incident appears to involve any of these risks, staff notify HRSA, MPSC leadership, and/or UNOS leadership and work with the member to implement an immediate containment plan as needed. Once any necessary containment plans have been implemented, patient safety staff send inquiry letters to all relevant parties to gather complete information about

[12] OPTN Policy 1.2: Definitions. "Eligible Death."
[13] OPTN Bylaws, Appendix B.5: OPO Personnel.
[14] OPTN Member Evaluation Plan.

the incident. At the conclusion of the investigation, staff present the results to a multi-disciplinary team that determines whether a potential OPTN policy or bylaw noncompliance occurred. If no potential noncompliance exists, the case is closed. If the team identifies a potential noncompliance, the member receives a notification letter explaining the potential policy or bylaw noncompliance and staff refers the case to the MPSC for review.

Aside from the key personnel requirements, OPTN Obligations do not specify a minimum number of staff required to be employed by an OPO. If the case were referred to the MPSC, the MPSC would use its own clinical expertise and medical judgment to determine whether the OPO met the requirement of having "necessary staff to recover and distribute organs according to OPTN obligations," or whether the OPO's current staffing structure is indicative of any systemic issues that raise patient safety concerns.[15]

c. What, if any, steps has UNOS taken in response to findings in HHS OIG audits that multiple OPOs charged Medicare for unallowable expenditures?

The OPTN is not authorized to monitor or enforce CMS Conditions for Coverage.

d. To what extent does the UNOS Membership & Professional Standards Committee (MPSC) conduct financial audits to ensure that all reported expenses in an OPO's Medicare Cost Reports are reasonable and focused on the OPO's mission of organ recovery? If the MPSC does not conduct any such audits, please explain why not.

The MPSC does not conduct financial audits. The OPTN is not authorized to monitor or enforce CMS Conditions for Coverage.

e. Is there an independent, third-party entity responsible for auditing each of the 58 OPOs to ensure that all costs are "reasonable," "necessary," "proper," and "allowable?" If so, please explain, including but not limited to the frequency with which such audits are conducted. If not, please explain why UNOS has not required any independent audits of OPOs.

UNOS and the OPTN do not require independent audits of OPOs for costs because cost reporting is not an OPTN Obligation, and the OPTN is not authorized to enforce non-OPTN obligations. To the best of UNOS's knowledge, such auditing would be conducted by CMS or by the Internal Revenue Service (or similar state agencies). If UNOS were to learn of unreasonable cost reporting through our incident handling process, we would refer the matter to HRSA for communication to CMS.

2. Over the last 10 years, how many OPOs have been identified by the Scientific Registry of Transplant Recipients (SRTR) as statistically significantly underperforming over any reporting period?

As explained in the answer to Question 1.a., an OPO comes under OPTN review if all three of the following criteria are met: 1) more than 10 fewer observed organs per 100 donors than the expected yield; 2) a ratio of observed to expected yield less than 0.90; and 3) a two-sided p-value less than 0.05. These criteria can be applied to each organ type or an aggregate of all organs, so an OPO could be identified in either category.

Since the OPTN began using these criteria for performance reviews in July 2012, the MPSC

[15] OPTN Bylaw Article 1.1.E: Member Compliance. "By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations, which include…(2) Acting to avoid risks to patient health or public safety."

has conducted reviews of 23 OPOs for lower than expected yield in at least one organ. The average time between initial inquiry by the MPSC and the OPO's release from review is 218 days.

3. **For each of these OPOs identified as statistically significantly underperforming by the SRTR, please provide a list of all instances of OPO underperformance in the last 10 years (as defined by statistical significance between the observed value and the expected value for the metrics reported on by the SRTR).**

   Since 2012, the OPTN has reviewed 23 different OPOs for performance under the metrics described in the responses to Questions 1.a. and 2.[16] Four of those 23 OPOs have been reviewed by the MPSC on more than one occasion, when their organ yield improved and they later met criteria for review again.

   Four OPOs have been identified for heart yield; nine for kidney yield; five for liver yield; five for lung yield; two for pancreas yield; and one for aggregate organ yield.

   Twelve reviews involved OPOs identified for only one data cohort; 18 reviews involved OPOs identified for two cohorts; two reviews involved OPOs identified for three cohorts; two reviews involved OPOs identified for four cohorts; and one review involved an OPO identified for five cohorts.

   a. **For each instance, please describe: [t]he OPO in question; whether the instance was formally presented to the MPSC and the corresponding date; the review process; the composition of the relevant MPSC subcommittee(s) that reviewed each case, including any conflicts of interest for each MPSC member; the findings of such process; the recommended course of action, including whether a corrective action plan was implemented; and whether the respective OPO's standing status was changed as a result of the instance.**

   Data responsive to these detailed questions are provided in the report referenced above.[17] The following information provides context for the data we provided.

   OPO performance review is conducted in a medical peer review setting, and following is our process for engaging with OPO members that come under performance review. Staff assign an ad hoc subcommittee of three to four reviewers for each case reviewed by the MPSC. Staff start with specific subject matter experts for the organ member type, then fill in with other MPSC members. Subject matter experts include physicians, surgeons, and administrators for hospital-related cases, OPO staff for OPO cases, and histocompatibility staff for lab-related cases. If a member has previously been under review, staff try to assign the same reviewers to the case for continuity.

   While choosing the ad hoc subcommittee, staff check for conflicts of interests and do not assign any cases to members with a conflict. MPSC members are considered to have a conflict with any case in which they have a personal or financial interest in the outcome. All MPSC members must disclose such conflicts of interests at the beginning of their terms, and during the year if a new conflict arises. In addition, an MPSC member is presumed to have a conflict of interests in any case involving an institution at which the committee member is

[16] Spreadsheet: OPOs Identified by the SRTR as Statistically Significantly Underperforming. Provided in Folder 3.
[17] *Id.*

currently employed, or located in the same donation service area (DSA), state, or OPTN Region as the committee member. There is also a presumed conflict if, within the last five years, the MPSC member has an advising, consulting, or mentoring relationship; has been previously employed or trained there; or trained individuals involved in the case.

If all reviewers on the ad hoc subcommittee vote in agreement, and the recommendation is to release, continue to monitor, or other non-adverse action, the case is added to the consent agenda for the next meeting of the MPSC. If the reviewers disagree or are recommending an interview, peer visit, or adverse action as defined in the OPTN Bylaws, the case is added to the discussion agenda for the next meeting of the MPSC. At its meeting, the MPSC reviews and votes on the consent agenda. MPSC members have an opportunity to remove an item from the consent agenda if they wish to discuss it before voting. After approving consent agenda items, the MPSC discusses and votes on each item on the discussion agenda.

When the MPSC considers members under review, it does not simply focus on sanctions. Instead, the MSPC's discussion largely centers on the feedback the MPSC wishes to provide to the member regarding how it can improve its performance, and what information, such as corrective action planning or quality improvement planning, that member can provide to the MPSC to assure that the member is working towards achieving such improvement.

4. What steps has UNOS taken to address delays and other issues of organ transportation, including to understand the impact of these issues on patient safety?

There are three primary functional areas that allocate significant resources to understand and address transportation issues and potential impacts on patient safety: the UNOS Patient Safety team, the OPTN Operations & Safety Committee, and the UNOS Organ Center.

The Patient Safety team is often the first to learn of potential patient safety issues, including those caused by transportation issues. The Patient Safety team typically learns about these types of events through various reporting mechanisms available to members and the public, including:

- An OPTN member submits a report through the Improving Patient Safety Portal in UNet
- A current or former OPTN member calls the member reporting telephone line
- A current or former OPTN member or concerned individual emails, faxes, or mails a correspondence
- A UNOS department refers a case or concern
- An automated safety monitoring report signals a potential safety incident
- Concerns are identified through publicly available information such as media reports, news articles, etc.

While the Patient Safety team focuses on the compliance aspects of potential transportation issues learned about through these intake processes and conducts its investigations under the peer review process, the UNOS Research Department aggregates de-identified, summarized reports of patient safety situations (including both adverse events and near misses) submitted into the OPTN Improving Patient Safety (IPS) portal, and deliver them to the OPTN Operations and Safety Committee (OSC), which is charged to "improve the quality, safety and efficiency of the organ donation and transplantation system."[18]

[18] Operations and Safety Committee. https://optn.transplant.hrsa.gov/members/committees/operations-and-safety-committee/ (Accessed on February 24, 2020).

The OSC reviews these patient safety reports on a semi-annual basis. The purpose is to help the committee identify safety gaps and to proactively address high frequency and/or high impact events with system improvements. The committee uses this information to develop mechanisms that increase awareness and promote members to take measures to prevent repeat occurrences. Since reporting is voluntary is thus subject to underreporting, the purpose of analyzing this data at this time is not to estimate the true, underlying error rates, but instead to identify if certain types of events are becoming more frequent or if certain types of events are associated with loss of organs. This analysis is primarily intended to help the committee understand what is currently being reported, increase the transplant community's awareness of the types of safety events that are occurring, foster increased reporting by the transplant community, and guide evolving refinements to the data analysis. The analysis serves as a foundation for the OSC to identify area(s) where the OPTN would benefit from system improvements.

Transportation of organs is an area where the OSC has sought continuously to gain more knowledge and work to address identified issues. In addition to reviewing patient safety data semiannually, the OSC has taken efforts to broaden its understanding of how organs are transported and the impact of transportation issues on the OPTN through surveys of the transplant community,[19,20] interviews,[21] and guest testimony at meetings. These activities have led to various types of proposed solutions including guidance, system operation changes, potential data collection and community education. In June 2019 the OSC prepared, and the OPTN Board of Directors approved, Guidance on Effective Practices in Broader Distribution.[22] This guidance document contains information on effective practices for communication during organ recovery and transportation for organ transfer to the transplant hospital. Findings from analyses of survey and interview data have been published in peer review journals,[23] and presented at various transplantation conferences as well.[24, 25] Most recently, in the Fall of 2019, the OSC sponsored a request for information during public comment to gather community input on requiring data collection on organ transportation mode and timing to be used to evaluate the logistical impacts of broader organ distribution.[26] This project is still underway and awaiting additional data from a pilot project to inform a future public comment policy and data collection proposal.

The OPTN also undertook a significant effort over the last decade to develop TransNet, a standardized organ coding and tracking system, and to require its use by OPOs.[27] TransNet automates the organ packaging and labeling process using a barcode system, as a measure of ensuring that organs are transplanted into the correct recipient.[28] Currently

[19] Transportation Survey. July 31, 2017. Provided in Folder 4.
[20] Transportation Survey Results. August 2017. Provided in Folder 4.
[21] Plane Transportation Questionnaire. August 27, 2018. Provided in Folder 4.
[22] Guidance on Effective Practices in Broader Distribution. https://optn.transplant.hrsa.gov/media/2993/osc_boardreport_201906.pdf (Accessed on February 24, 2020).
[23] Stewart, D.E., Tlusty, S.M., Taylor, K.H., Brown, R.S., Neil, H.N., Klassen, D.K., Davis, J.A., Daly, T.M., Camp, P.C. and Doyle, A.M. (2015), Trends and Patterns in Reporting of Patient Safety Situations in Transplantation. American Journal of Transplantation, 15: 3123-3133. doi:10.1111/ajt.13528. Provided in Folder 4.
[24] Stewart, Zoe, et. al. Poster: "Systems and Human Errors are the Major Causes of Organ Transportation Failures and Resultant Discard of Transplantable Organs." American Transplant Congress 2012. Provided in Folder 4.
[25] Marvin, Michael, et. al. Poster: A Current Assessment of the Travel Policies and Procedures for Organ Recovery. Transplant Management Forum 2018. Provided in Folder 4.
[26] OPTN Public Comment Proposal: Data Collection to Evaluate the Logistical Impact of Broader Distribution. https://optn.transplant.hrsa.gov/governance/public-comment/data-collection-to-evaluate-the-logistical-impact-of-broader-distribution/ (Accessed on February 24, 2020).
[27] OPTN Briefing Paper: Standardize an Organ Coding System for Tracking of Organs: Requirement for OPO TransNet Use. https://optn.transplant.hrsa.gov/media/1862/osc_briefingpaper_201606.pdf (Accessed on February 24, 2020).
[28] TransNet℠. https://unos.org/technology/transnet/ (Accessed on February 28, 2020).

OPOs scan organs when packaging is completed and the organs are ready for transport. The OPTN is exploring ways in which the TransNet technology could be enhanced to integrate global positioning software (GPS) devices and third-party applications.

UNOS also recently announced a new project to partner with OPOs throughout the country and the travel and logistics providers the OPOs use to conduct a "real-time data analysis to refine a feasibility algorithm aimed at predicting the optimal route for organ transplantation."[29]

Finally, NOTA directs that a significant function of the OPTN is to "maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list."[30] The OPTN Contract requirement interpreting this provision requires UNOS to maintain a 24-hour operations center, which UNOS fulfills through the UNOS Organ Center. The UNOS Organ Center is available to assist with transportation of organs as requested by OPTN members. The UNOS Organ Center 24-hour phone number is printed on each OPTN required shipping label. This allows for any individual with a question or concern about a shipment or its routing to reach UNOS Organ Center staff at any time. When contacted, staff help to troubleshoot the issue in real time with the caller by connecting them with the appropriate sender, logistics providers, or receiver of the shipment. When transportation arrangements are facilitated by the UNOS Organ Center, each OPO has the option to use their own preferred logistics providers, allowing them to select the best providers for their particular needs.

For those situations in which the Organ Center has been called upon to assist with facilitating transportation (approximately 4% of the total number of organs recovered for transplant nationally), Organ Center staff retrospectively review each instance. The data are captured electronically, allowing for monthly aggregate data and narrative examples of transportation issues for Organ Center-facilitated shipments (which include both organ and non-organ shipments) to be included in reports to HRSA in order for HRSA to provide required oversight. Similar data were also provided the OSC for use in their committee work.

The UNOS Organ Center significantly improved its ability to collect and store more specific data when it implemented an online transportation form and underlying database form in late June of 2016. While this system was not specifically designed to track and trend transportation problems, it nevertheless created system that can count and store those data.[31] These data are relevant, but also limited; the data are input and reviewed by UNOS staff (not externally validated by the travel or logistics providers), and only include the small subset of transportations facilitated by the Organ Center for unaccompanied organs (98% of which are kidneys) that are moved in insulated disposable shipping boxes (in accordance with OPTN policy for shipping organs).

a. Please provide all documentation related to every instance, within the last 10 years, in which an organ was lost, delayed, damaged, or otherwise mishandled in transit, including the cause of the incident, the manner in which the incident was disclosed to the recipient and the family of the deceased donor, and all information related to the clinical impact these incidents have on recipients.

[29] Dreyfuss, Anne. "An Expedia for organ transplantation: Predicting travel time." https://unos.org/news/innovation/an-expedia-for-organ-transplantation/ (Accessed on Feb. 25, 2020).
[30] National Organ Transplant Act. 42 U.S.C. §274(b)(2)(C).
[31] Emily Harris, "Lost in Transplantation," REVEAL NEWS & PRX (Feb. 8, 2020), available at https://www.revealnews.org/episodes/lost-in-transplantation/ (Accessed on February 26, 2020).

You request information relative to all organs that are "lost, delayed, damaged, or otherwise mishandled in transit." The data provided in response to these sub-questions are necessarily limited to only the small subset of organ transportation arrangements that were facilitated by the UNOS Organ Center, because the OPTN does not collect "transportation data" on a national, systematic basis. It is important to acknowledge that the vast majority of organ transportation arrangements are not facilitated by the UNOS Organ Center. As noted in the recent Kaiser Health News article, "Matters involving the transportation methods used by organ procurement organizations (OPOs) are arranged directly between OPOs and transplant centers.""[32]

The data collected by the UNOS Organ Center have several limitations. As noted above, the data have only been captured in this format since June 2016. The data include only information relative to shipments facilitated by the UNOS Organ Center and those data are not collected in a format that would demonstrate that organs that were "lost, delayed, damaged, or otherwise mishandled in transit." Rather, staff retrospectively document a "transportation issue" when an organ failed to reach its original intended destination within two hours of the original anticipated arrival time. So a "transportation issue" would include organs that were delayed and/or potentially mishandled in transit, but would not specifically capture an organ that was lost or damaged. When a "transportation issue" is identified, staff document and log the reason. As noted earlier, an important limitation of the data is the lack of any external validation of the staff-documented reasons by the commercial airlines or other logistics providers involved in the transportation. These data are provided in Tables 1 and 2, below.

In Table 4.a.1, we have provided data demonstrating the ever-increasing total number of organs recovered for transplant every year, and the relatively small percentage of those organs for which the Organ Center facilitated transportation. Smaller still is the number of organs for which the Organ Center facilitated transportation and for which staff documented a transportation issue. The final disposition of the organs – whether transplanted or not – is also included, and those data are segmented by whether or not a transportation issue was documented. Among the 409 organ transportations facilitated by the UNOS Organ Center where a transportation issue was documented, the yearly percentage of organs transplanted ranged from 60.7% to 73.9%. In the 5,658 organ transportations facilitated by the UNOS Organ Center with no documented transportation issue, the yearly percentage of organs transplanted ranged from 72.7% to 73.3%.

[32] JoNel Aleccia, "How Lifesaving Organs for Transplant Go Missing in Transit," KAISER HEALTH NEWS (Feb. 10, 2020), available at https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/ (Accessed on February 26, 2020).

Table 4.a.1: UNOS Organ Center deceased donor organ transportation summary

	2016*		2017		2018		2019	
	N	%	N	%	N	%	N	%
Total Number of Organs Recovered for Transplant Nationally	35,361†		36,424		37,851		41,706	
Total Transportations Facilitated by the Organ Center								
Total deceased donor organ transportations facilitated by the Organ Center	986	100.0%	1,617	100.0%	1,715	100.0%	1,749	100.0%
Total Transportations Facilitated by the Organ Center by Allocation								
Allocated by the Organ Center	830	84.2%	1,431	88.5%	1,608	93.8%	1,616	92.4%
Allocated by an OPO	156	15.8%	186	11.5%	107	6.2%	133	7.6%
Total Transportations Facilitated by the Organ Center by Transportation Documentation								
No transportation issue documented	**927**	**94.0%**	**1,525**	**94.3%**	**1,598**	**93.2%**	**1,608**	**91.9%**
Transplanted	679	73.2%	1110	72.7%	1178	73.3%	1173	72.9%
Not Transplanted	249	26.8%	417	27.3%	428	26.7%	437	27.1%
Transportation issue documented	**59**	**6.0%**	**92**	**5.7%**	**117**	**6.8%**	**141**	**8.1%**
Transplanted	41	69.5%	68	73.9%	71	60.7%	96	68.1%
Not Transplanted	18	30.5%	24	26.1%	46	39.3%	45	31.9%

* Collection began June 27, 2016 unless otherwise noted
† Full years' worth of data, 1/1/2016 – 12/31/2016

As detailed in Table 4.a.1, the percentage of organs transplanted where transportation was facilitated by the Organ Center and a transportation issue was documented, ranged between 60.7% to 73.9%. It must be noted that it is not possible to determine whether or not a documented transportation issue was a factor in the transplant program's final decision whether to transplant an organ.

Table 4.a.2 details the causes and final dispositions for the small number of organ transportations facilitated by the Organ Center where a transportation issue was documented. The highest number of transportation issues were related to commercial flights; specifically flight delays or cancellations. Courier related transportation issues were the second most frequent cause, followed by sender/receiver issues; most commonly packages not ready or incorrect addresses.

Table 4.a.2: Detailed causes of Organ Center facilitated deceased donor organ transportation issues and outcomes

	2016*			2017			2018			2019		
	N	TXed	Not TXed	N	TXed	Not TXed	N	TXed	Not TXed	N	TXed	Not TXed
Commercial Flight												
All Reasons	**35**	**26**	**9**	**52**	**36**	**16**	**52**	**33**	**19**	**61**	**41**	**20**
Flight Delay or Cancellation	31	23	8	40	28	12	34	23	11	38	26	12
Onload or Offload Error	4	3	1	7	5	2	9	4	5	5	3	2
Other	0	0	0	5	3	2	9	6	3	18	12	6
Courier												
All Reasons	**14**	**8**	**6**	**29**	**22**	**7**	**51**	**32**	**19**	**57**	**42**	**15**
Late, Delayed, or not Available	6	3	3	12	8	4	20	16	4	24	14	10
Timing, Address, or Routing Information	2	2	0	13	10	3	15	6	9	19	18	1
Other	6	3	3	4	4	0	16	10	6	14	10	4
Sender/Receiver												
All Reasons	**10**	**7**	**3**	**11**	**10**	**1**	**14**	**6**	**8**	**23**	**13**	**10**
Package not Ready or Incorrect Address	8	6	2	7	7	0	9	5	4	16	7	9
Labelling or Packaging Issue	1	0	1	0	0	0	2	0	2	0	0	0
Other	1	1	0	4	3	1	3	1	2	7	6	1

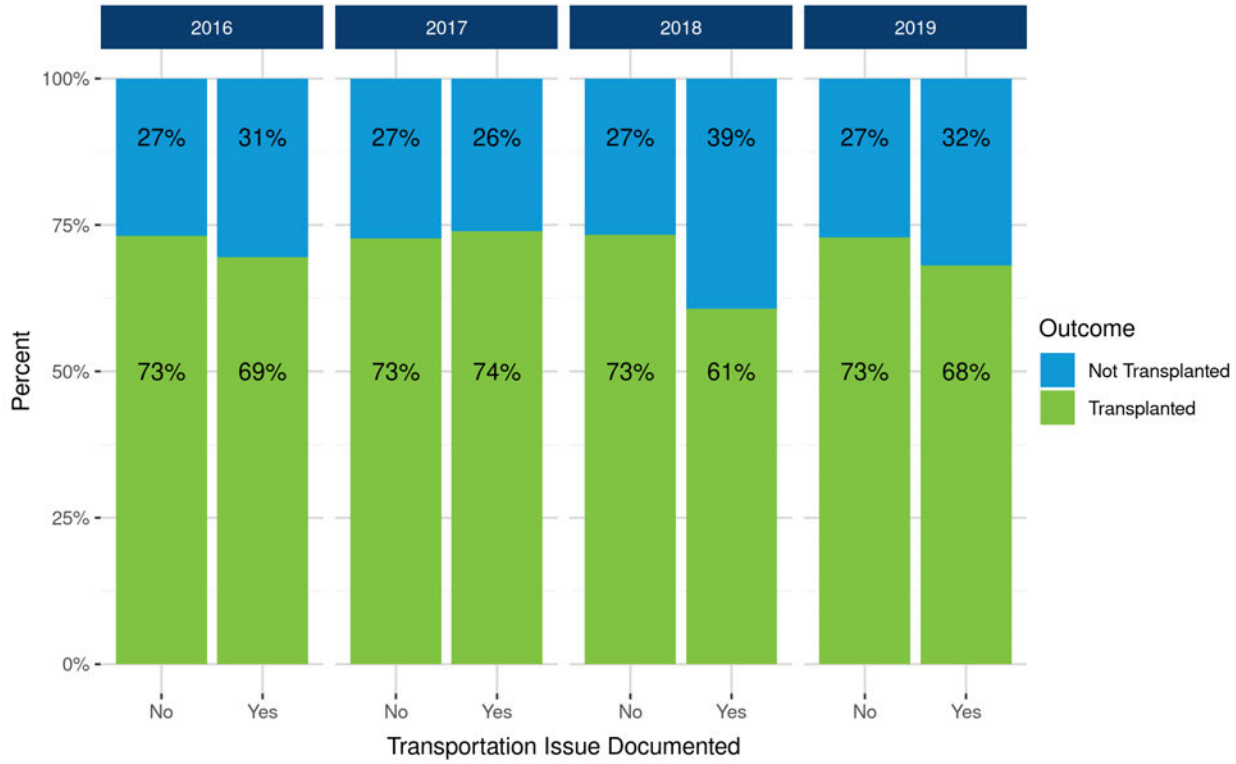
Collection began June 27, 2016

Neither UNOS nor the OPTN have any data available that would demonstrate "the manner in which the incident was disclosed to the recipient and the family of the deceased donor," nor any "information related to the clinical impact these incidents have on recipients." Disclosure to the family is entirely within the discretion of either the OPO or the transplant program, and the OPTN does not maintain any policies or bylaws on this topic.

As to the clinical impact of transportation issues on recipients: as noted above, it is not possible to draw any absolute conclusions about the association between an incident that may have occurred in transit and the ultimate outcome of the transplant. Most organs that experienced "transportation issues" were transplanted, and some were not, and some that did not experience a "transportation issue" were not transplanted, but most were. Annually less than 10% of organ transportations facilitated by the Organ Center documented a transportation issue. Of those, the yearly percentage of organs transplanted ranged from 60.7% to 73.9%. In the over 90% of

organ transportations facilitated by the Organ Center without a transportation issue documented, the yearly percentage of organs transplanted ranged from 72.7% to 73.3%.

Figure 4.a.1: Summary of UNOS Organ Center deceased donor organ transportation by transportation issue and whether the organ was transplanted.



There are many reasons why a transplant program may not ultimately transplant an organ it accepted for a recipient, including: too much cold ischemic time (which may or may not be due to a transportation issue); the anatomy or appearance of the organ upon arrival (which may or may not be due to a transportation issue); or even a change in the health of the recipient that may make them unsuitable for the scheduled transplant. The same reasons can also be true for organs without any "transportation issues." For all the same reasons (cold ischemic time, anatomy of the organ, health of the recipient) and many others not listed, the transplant surgery may still not occur.

UNOS supports the efforts of Congress to question, collect relevant data, and seek to improve the nationwide capability to allow for OPOs and hospitals to more effectively and efficiently transport organs.

b. For each instance, please also indicate whether the organ was allocated by the UNOS Organ Center or the corresponding OPO.

See Table 4.a.1, above.

5. Please provide data on the number of organs eligible for transplant that were recovered for transplant but not transplanted in the last 10 years, including the types of organs, the designated service areas (DSAs), and OPOs.

These data are provided to you in a separate spreadsheet.[33] All data are based on actual deceased donors from whom at least one organ was recovered for the purpose of transplant. For each donor, the disposition of each organ is entered. The data examine the organs that were recovered for transplant and subsequently transplanted or not transplanted. There are times when organs that are recovered but not accepted for transplant by a transplant program may be used for research if accepted into a research protocol. Others may not be used at all. The reasons an organ that is recovered for transplant but not transplanted are often multi-factorial. The reason provided to the OPTN by the OPO is the reason determined by the OPO to best fit the situation from the options provided.

a. Please include all data related to the reasons why recovered organs were discarded.

These data are also included in the separate spreadsheet referenced above.[34] The number and percent of kidneys recovered for transplant but not transplanted is the largest of all of the organs. While OPOs try to place all organs prior to going to the operating room to recover the organs, kidney placement attempts often continue even after the donor moves to the OR. If an OPO believes that kidneys have even a remote chance of being transplanted, it will recover those kidneys while placement continues. In stark contrast, hearts and lungs are rarely recovered for transplant unless an OPO has received an acceptance from a transplant program. Then, the heart transplant or lung transplant team will come to the donor hospital to perform the recovery procedure and personally transport the organs back to the transplant hospital where the candidate awaits.
Organs recovered for transplant but not transplanted are not necessarily “discarded.” Some of these organs are referred for research.

6. In light of HHS OIG and Government Accountability Office (GAO) findings, as well as public reporting about various OPO improprieties (some of which resulted in prison sentences for OPO executives, misuse of taxpayer dollars, life-threatening patient safety issues, and troubling tissue recovery practices), please provide:

a. A list of any OPOs that have been accorded probationary status or named a "Member Not in Good Standing," including dates on which each such OPO's status changed.

The OPTN may impose a range of actions based on a member’s failure to comply with OPTN Obligations.[35] Probation and Member Not in Good Standing are the two adverse actions that the OPTN Board can impose that also require public notification. Throughout the history of the OPTN, three OPOs have been placed on Probation, and two OPOs have been determined to be a Member Not in Good Standing as follows in Table 6.a.1.

[33] Eligible Organs and Not Transplanted Data. Provided in Folder 5.
[34] *Id.*
[35] OPTN Bylaw L.2: OPTN Actions. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (Accessed on February 26, 2020).

Table 6.a.1: OPO Members that have experienced Adverse Actions

OPO Name	OPTN Sanction	Date of Sanction	Date Released from Sanction
New Mexico Donor Services	Probation	Nov-13	Jun-15
Nebraska Organ Recovery System	Probation	Nov-14	Jun-16
Indiana Donor Network	Probation	Dec-16	May-18
Nevada Donor Network	Member Not in Good Standing	Jul-11	Jun-13
Life Alliance Organ Recovery Agency	Member Not in Good Standing	Dec-15	Dec-17

The press releases announcing each member's sanction and release from sanction are accessible from the hyperlinks contained within the table above.[36]

b. All materials related to the OPTN's fact-finding process with respect to any OPO that has ever been put on probation or listed as a "Member Not in Good Standing" by the OPTN, including all materials, reports, memos, audits, and correspondence relating to this process.

As previously explained, we respectfully cannot provide these materials because they are privileged, confidential medical peer review information.

The Final Rule requires that the OPTN use the peer review process to review membership applications, and to conduct periodic and ongoing reviews of member compliance with OPTN obligations. MPSC members are considered to be Medical Peer Reviewers. Peer review privilege is important because it:

- Provides a "safe space" for members to share information about events at their institutions
- Permits full disclosure so the OPTN can effectively monitor member compliance
- Permits full disclosure so the OPTN can help members improve performance for the benefit of patient health and public safety
- Encourages peer reviewers to participate without fear of legal reprisal

Peer review protections are jointly held and cannot be unilaterally waived by one party. Both the member and the OPTN must keep all deliberations, recommendations, and actions of the MPSC and Board of Directors confidential in accordance with applicable medical peer review requirements.

c. All complaints made regarding (or violations alleged against) OPOs that have been reported to UNOS, including those considered to be protected under peer review, both including cases referred and not referred to the MPSC, including all UNOS correspondence and corrective action plans,

[36] Press releases are also provided in Folder 6.

meeting minutes, and any other written records from MPSC deliberations related to those incidents.

As previously explained, we respectfully cannot provide these materials because they are privileged, confidential medical peer review information. The success of our member improvement processes are critically dependent on the trust our members have in the confidentiality of this process.

While the MPSC cannot discuss the specifics of cases in order to help other programs avoid those particular problems, it is committed to searching for common themes and areas of weakness that can lead to general news articles, education events, or policy changes. UNOS staff often partner with MPSC members and with members who have interacted with the MPSC to present lessons and improvements that have been achieved as a result of the interactions. These presentations often occur at transplant conferences.[37]

d. The names (and corresponding professional affiliations) of each individual that has ever served as chairperson of (1) the MPSC, and/or (2) the OPO subcommittee. (Please also provide a list of all members of the relevant MPSC subcommittee(s), and anyone else involved in the decision-making process regarding whether or not to investigate each complaint at the time of the referral or non-referral.)

The requested roster information is provided in spreadsheets in Folder 6.[38] In subsection (e) below, we further explain the MPSC's structure and how committee members are assigned to review various case types.

e. A description of the MPSC's overall structure (as well as its subcommittee structure), including how the oversight and investigatory responsibilities are apportioned between and among the various committees and subcommittees, as well as the process by which complaints are directed to various subcommittees or committees of MPSC.

MPSC Overall Structure:
The Membership and Professional Standards Committee (MPSC) is the OPTN committee charged with ensuring that OPTN members meet and maintain compliance with OPTN Obligations, including OPTN Policies and Bylaws. This means the MPSC develops and recommends membership criteria for each class of OPTN membership, recommends changes to membership requirements when necessary, and reviews member applications and makes recommendations to the OPTN Board of Directors. Additionally, the MPSC reviews member compliance with OPTN obligations.

The MPSC is made up of 38 voting members, including a Chair and Vice-Chair, 11 elected regional representatives known as Associate Councilors, and at-large representatives to promote representation from each area of specialty. These members are transplant surgeons and physicians, OPO director and staff, transplant administrators, lab directors, living donor representatives, transplant recipients, or donor family members. Each member of the MPSC signs a confidentiality agreement when appointed to the Committee.

[37] We have provided examples of these presentations in Folder 6.
[38] Current MPSC Roster and Historical MPSC and Subcommittee Rosters provided in Folder 6.

The Associate Councilors are elected by their OPTN Region. Associate Councilors normally join the Board of Directors after a 2 year term on the MPSC. The At-Large Representatives often serve to represent a particular profession or background as subject matter experts, such as transplant coordinators, transplant recipients, or histocompatibility labs. All MPSC members provide their expertise on bylaws and policy, and represent the MPSC as needed through professional organizations like NATCO, ASTS, or AOPO.

HRSA representatives, as well as the Vice-President of the OPTN Board of Directors are ex-officio, non-voting members of the MPSC. HRSA Ex-Officio Representatives act as the liaison to the federal government, and monitor activity for adherence to NOTA, the Final Rule, and the OPTN contract. They make sure that the OPTN and SRTR contractors are working effectively and that policy and implementation comply with government expectations. They coordinate the OPTN with other parts of government.

MPSC Standing Subcommittees:
Prior to June 2019, the MPSC had two standing subcommittees. Each MPSC member was assigned to one of the subcommittees. The Performance Analysis and Improvement Subcommittee (PAIS) focused on reviews of transplant program performance, including transplant outcomes and functional inactivity. The Policy Compliance Subcommittee (PCSC) reviewed investigations of potential policy noncompliance, routine UNOS staff site survey results, and the allocation of every transplanted organ. The full MPSC would review membership applications, OPO performance, and living donor events.

In an effort to allow for all MPSC members to have the opportunity to review all types of cases, the MPSC eliminated its PAIS and PCSC in June 2019. Each MPSC member is now exposed to the details of all types of cases. In addition, this change will allow the MPSC to move to a more holistic review of members and reviewing any issues with a member in a single discussion. The MPSC may form subcommittees to work on long term projects. Currently, the MPSC has one subcommittee, the Membership Requirements Revision Subcommittee. This subcommittee is leading a project that involves reviewing the current OPTN Bylaws around membership requirements and proposing changes to the requirements.

The MPSC may also form short term subcommittees or work groups to review specific members or to discuss changes to the MPSC review process. Any member who received an adverse action would have a subcommittee that led the discussions of its progress. The MPSC's work to define the process for OPO Performance review involved a work group consisting of all the MPSC members who worked at an OPO.

How the MPSC conducts reviews:
The MPSC reviews hundreds of member-specific issues each year. These are confidential medical peer reviews and are conducted in closed session. OPTN Bylaws Appendix L (Reviews and Actions) provides guidance and a framework for MPSC review. Appendix L also outlines members' rights when the MPSC or OPTN Board of Directors is considering taking certain actions.

To efficiently perform this large amount of work, the MPSC typically forms small, ad hoc subcommittees of three or four MPSC members. The subcommittee performs an initial review of the matter and makes recommendations to the full MPSC. The MPSC then reviews and discusses the recommendations during conference calls and in-person meetings. Generally, if the ad hoc subcommittee unanimously agrees on a standard recommendation, the item will be added to a consent agenda. The MPSC receives a report of all items on the consent agenda,

and any committee member may request any consent agenda item be moved to discussion. Any disagreement or any unusual recommendations are also on the discussion agenda. For each discussion topic, staff typically provide a high-level overview of the issue under consideration and reviews the committee's options. The MPSC Chair then calls on the ad hoc subcommittee members to begin the discussion. The full MPSC most vote on the recommendations for all issues. A typical in-person meeting agenda might include actions on as many as 350 members, programs, or applicants.

Types of monitoring include:

- Transplant program performance such as patient outcomes and activity levels
- OPO donor yield performance
- Living donor events
- Allocation reviews
- Site surveys
- Reports of member noncompliance with OPTN policy submitted through the UNet Improving Patient Safety Portal

Factors the MPSC considers when determining an appropriate action include:

- Has the member demonstrated an awareness of and accountability for the noncompliance?
- Did the member self-report the noncompliance?
- Did the member take corrective action when learning of the noncompliance?
- Does the noncompliance pose an urgent and severe risk to patient health or public safety?
- Does the noncompliance pose or fail to avoid a substantial risk to the integrity of or trust in the OPTN?
- Do patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the noncompliance occurred?
- Does the noncompliance demonstrate lack of stewardship of donated organs?
- Is the noncompliance likely to recur?
- Has the member demonstrated previous and ongoing compliance with OPTN Obligations?

Peer Review and Conflicts of Interests:
The Final Rule requires that the OPTN use the peer review process to review membership applications, and to conduct periodic and ongoing reviews of member compliance with OPTN obligations. MPSC members are considered to be Medical Peer Reviewers. Peer review privilege is important because it:

- Provides a "safe space" for members to share information about events at their institutions
- Permits full disclosure so the OPTN can effectively monitor member compliance
- Permits full disclosure so the OPTN can help members improve performance for the benefit of patient health and public safety
- Encourages peer reviewers to participate without fear of legal reprisal

Peer review protections are jointly held and cannot be unilaterally waived by one party. Both the member and the OPTN must keep all deliberations, recommendations, and actions of the MPSC and Board of Directors confidential in accordance with applicable medical peer review

requirements. Confidentiality extends beyond the review process to even after the deliberations and actions have concluded.

Along with maintaining confidentiality, it is equally important to avoid conflicts of interests. MPSC members are considered to have a conflict with any case in which they have a personal or financial interest in the outcome. All MPSC members must disclose such conflicts of interest at the beginning of their term when they complete an agreement or during the year if a new conflict arises. In addition, an MPSC member is presumed to have a conflict of interest in any case involving an institution:

- at which the committee member is currently employed, or
- located in the same DSA, state, or Region as the committee member,

The MPSC also recognizes that there are some gray areas where timing and context are relevant to determining a conflict of interest. There is a presumed conflict if, within the last five years, the MPSC member has:

- an advising, consulting, or mentoring relationship,
- has been previously employed or trained there, or
- trained individuals involved in the case

If one of these criteria were met more than five years ago, there is no presumption of conflict unless the MPSC member has a personal or financial interest. MPSC members are instructed to assume that they are conflicted if they are unsure whether a conflict exists. MPSC members are also encouraged to speak if they believe that another member of the committee has a conflict with a matter.

7. Given that multiple OPOs recover tissue and some operate tissue banks, on what mechanisms does UNOS rely to minimize conflicts of interest, and what measures does UNOS take to protect against OPOs prioritizing tissue recovery over organ recovery due to financial incentives?

In general, UNOS manages conflicts of interests in multiple ways. Each year, as an OPTN Contract deliverable, UNOS submits to HRSA a Conflicts of Interests Mitigation Plan. This plan details all the ways in which UNOS minimizes conflicts of interests amongst Directors of the OPTN Board and their employers, UNOS, and any other personal or financial interests with which the Directory may be presented with a conflict. As a condition of service, Directors must sign an OPTN attestation document annually.[39] All Board and committee volunteers must also sign the OPTN conflicts of interest and confidentiality agreement annually, and disclose conflicts on an ad hoc basis as they arise.[40] The OPTN Bylaws also address conflicts of interests for Directors.[41]

UNOS and the OPTN do not have specific conflicts of interests policies with regard to members and the work they perform on a daily basis.

To the extent that this question implies that there are reasons an OPO would have a conflict of interests or financial incentive to prioritize tissue recovery instead of organ recovery, and to perhaps not recover both, the implication is not grounded in the practical reality of organ and

[39] OPTN Board of Directors Attestation. https://rcunos.unos.org/surveys/?s=KJR9M38JCK (Accessed on February 27, 2020). Provided in Folder 7.
[40] Confidentiality Agreement and Certification Regarding Conflicts of Interests. https://rcunos.unos.org/surveys/?s=XP39XPX3DA Accessed on February 27, 2020). Provided in Folder 7.
[41] OPTN Bylaw Article 2.7: Conflicts of Interest.

tissue recovery. As explained below, there is no incentive for OPOs to prioritize recovery of tissue.

a. Under what circumstances might financial incentives to recover tissue create a conflict of interest for an OPO? In the event that such a conflict arises, how does UNOS ensure that it is resolved?

Organ donation and transplantation occurs in a compressed timeframe with a high sense of urgency, since once circulation ceases, the organ quality and viability for transplantation deteriorate rapidly. In contrast, tissue recovery can occur up to 24 hours after cessation of circulation. This is the reason that, for a donor that is able to donate organs and tissue, the recovery of organs happens first. The time that it takes to do the organ recovery leaves ample time for tissue recovery, so there is no need to choose between the two or prioritize tissue recovery over organ recovery.

There are physiological conditions that may make a donor a tissue only donor, such as if the patient is asystolic at the time an OPO is called. Additionally, there are conditions that would make a donor an organ alone donor, such a patient with HCV positivity which may preclude any sort of tissue recovery but still allow for organ recovery. However, if a donor's condition would allow both organ and tissue donation, organ donation will always be prioritized above any other type of recovery due to physiologic reasons caused by cessation of circulation, in addition to the fact that organ donation and transplantation is a life-saving procedure.

UNOS and the OPTN do not have specific policies or bylaws with regard to prioritizing organ recovery over tissue recovery.

b. Please provide a list of each OPO currently operating a tissue bank. For OPOs that do not operate a tissue bank, please list any tissue-related companies with which they are affiliated.

UNOS and the OPTN do not collect any of the information you seek in this question.

c. To what extent and how are the nature of OPO relationships with tissue companies disclosed to donor families as well as the general public?

UNOS and the OPTN do not collect any of the information you seek in this question.

8. For each of the 58 OPOs, please provide the amount of compensation received by its chief executive officer (CEO) and its chief operating officer (COO) from the OPO or affiliated organization(s) (e.g., the OPO's foundation).

a. For each such CEO and COO, provide a breakdown of the compensation received from the OPO and/or affiliated organization(s) based on annual salary, bonuses, or other forms of compensation.

b. For each such CEO and COO, please disclose any business, entity, customer, supplier, contractor, or partner with which the OPO had a contract or financial relationship (e.g., tissue processors, cornea banks, funeral homes, OPO foundations, histocompatibility labs,40 aviation companies, etc.), including but not limited to salary, consulting fees, sales commissions, or equity interests, and list the exact breakdown of compensation the CEO or COO receives.

c. How are these financial relationships disclosed to Federal entities and the public?

UNOS and the OPTN do not collect any of the information you seek in this question and its subparts.

9. Given that some OPOs provide financial compensation for their board members (beyond reasonable expenses for board-related activities and travel/lodging), please provide a list of which of the 58 OPOs compensate their board members, including via contracts or other relationships with external organizations with which the board member maintains a relationship, and the exact amount of compensation received by those board members.

UNOS and the OPTN do not collect the information you seek in this question.

10. Which OPOs, or organizations affiliated with OPOs (e.g., TxJet) own, operate, or otherwise maintain a private plane? If multiple OPOs, jointly own, operate, or otherwise maintain a private plane, or a parent organization owning multiple OPOs (e.g., DCI Donor Services) owns, operates, or otherwise maintains a private plane, or if an OPO leases any of their planes to another OPO, transplant center, or other organization, please explain.

a. How does UNOS ensure that these private planes are not used for flights that are not directly related to recovering or transplanting an organ?

b. For each flight, please indicate whether there is a corresponding UNOS ID number. For any flight, or any leg of a flight, that does not have a corresponding UNOS ID number, please state the purpose for each leg of the flight-such as "maintenance," or "OPO employees fly to conference," or "personal travel for the CEO of the OPO."

c. If a private plane is used for unrelated purposes, such as to attend conferences, fundraisers, or for an OPO employee's personal travel, please provide documentation showing to what entity each leg of the flight was billed.

UNOS and the OPTN do not collect any of the information you seek in this question and its subparts.