OPTN/UNOS Thoracic Organ Transplantation Committee Meeting Minutes November 1, 2018 Chicago, IL

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Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToTraining teleconference and in-person in Chicago, IL on 11/01/2018 to discuss the following agenda items:

- 1. Eliminate the Use of Donor Service Areas (DSAs) in Thoracic Distribution
- 2. Modifications to the Adult Heart Allocation System
- 3. Modifications to the Distribution of Deceased Donor Lungs
- 4. Collection of Ex Vivo Lung Perfusion (EVLP) Data on the Deceased Donor Registration form (DDR) and Transplant Recipient Registration form (TRR)
- 5. Collection of Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates

The following is a summary of the Committee's discussions.

1. Eliminate the Use of Donor Service Areas (DSAs) in Thoracic Distribution

On August 13, 2018, the Organ Procurement and Transplantation Network (OPTN) Board of Directors submitted a plan to the Secretary of Health and Human Services to remove DSAs and OPTN regions as units of allocation from all organ allocation systems. OPTN has committed to a multi-step plan to eliminate use of DSAs in heart distribution in a deliberative manner and within a timeframe that will reduce the likelihood of unintended consequences.

As requested by the OPTN/UNOS Thoracic Organ Transplantation Committee ("Committee"), the Scientific Registry of Transplant Recipients (SRTR) staff presented Thoracic Simulated Allocation Model (TSAM) modeling results for DSA-free models of heart allocation. The Committee discussed the modeling and debated the predicted advantages and disadvantages of each option.

Data summary

- Overall, simulated waitlist and post-transplant outcomes differed little across the five simulations.
 - Transplant rates and counts, waitlist mortality rates and counts, and posttransplant mortality rates and counts were similar in DSA-first vs. DSA-free simulations.
 - Median distances donor organs traveled increased with increasing circle sizes. The DSA first and 250NM simulations were generally similar, the 150NM simulation showed shorter travel distances, and the 500NM-A and 500NM-B simulations showed the longest travel distances.
- The overall pattern was largely repeated in most subgroups: Results were similar by age (adult and pediatric age groups), sex, race and ethnicity, diagnosis, urbanicity, insurance at listing, location in the US (east/west), by center volume, and by distance.
- Exceptions to the above:
 - Most regions differed little in waitlist and post-transplant outcomes across simulations but some differences did occur.

- In regions 1 and 9, transplant rates were higher in 500NM-A and 500NM-B simulations than in DSA-first.
- In region 2, transplant rates decreased in the 150NM, 250NM, and 500NM-B simulations compared with DSA-first.
- In region 1, the number of waitlist deaths declined from 33 to 26 in the DSA-first to the 500NM-A simulation.
- Outcomes by adult status group showed some variation.
 - Among status 1 and 2 candidates, transplant rates increased in the 500NM-A simulation.
 - Among status 3 candidates, transplant rates increased in 250NM, 500NM-A, and 500NM-B simulations compared with DSA-first.
 - Among status 4 candidates, transplant rates decreased in 250NM, 500NM-A, and 500NM-B simulations compared with DSA-first.
 - Waitlist death counts declined for status 7 (inactive) candidates in the 500NM-A and 500NM-B simulations.
- Most outcomes differed little by pediatric status group, but among pediatric status 1A candidates, transplant rates increased in the 500NM-A and 500NM-B simulations compared with DSA-first.
- Transplant rates for blood type A candidates declined in the 250NM, 500NM-A, and 500NM-B simulations compared with DSA-first, and increased for blood type O candidates in the 500NM-A and 500NM-B simulations.
- Data by annual center volume were generally similar to overall data patterns, but transplant rates were lower in the 500NM-A and 500NM-B simulations for centers performing 25-50 transplants per year.
- Transplant counts by DSA shifted somewhat from the DSA-first to DSA-free simulations.
 - Most DSAs gained or lost fewer than 10 transplants, compared with DSAfirst, in any DSA-free simulation.
 - The largest increase was 24 more transplants in the 500NM-A simulation. The largest decrease was 32 fewer in the 250NM-simulation. These occurred in two nearby DSAs, each of which contained more than one heart transplant program.
- Shifts in transplant counts by state mirrored shifts by DSA.
 - Most states gained or lost fewer than 10 transplants, compared with DSAfirst, in any DSA-free simulation.
 - The largest increase was 33 more transplants among New Yorkers in the 500NMA simulation, and the largest decrease was 26 fewer among Pennsylvanians in the 250NM simulation. These occurred in two neighboring states, each with more than one transplant program.

Summary of discussion

The Committee debated the merits and disadvantages of each model. They referred to Table 1 and 2 as a reference during discussions.

Table 1: Five simulations in brief

| Name | Description |
|---------|--|
| DSA | Approved policy. Except in cases of broader sharing, local DSA is the first unit of allocation. |
| 150NM | Replace DSA with 150 NM as first unit of allocation. Adult status 1 and 2 and pediatric status 1A continue to receive offers of adult organs out to 500 NM. |
| 250NM | Replace DSA with 250 NM as first unit of allocation. Adult status 1 and 2 and pediatric status 1A continue to receive offers of adult organs out to 500 NM. |
| 500NM-A | Replace DSA with 500 NM as first unit of allocation. To maintain broader sharing, first offers of adult donor organs to adult status 1 and 2 and pediatric status 1A candidates go out to 1000 NM. Subsequent orderings for those candidates are similarly incremented. |
| 500NM-B | Replace DSA with 500 NM as the first unit of allocation. Adult status 1 and 2 and pediatric status 1A candidates are no longer eligible for broader sharing. Offer orders is: 1) status 1 adults and status 1A children within 500 NM, 2) status 2 adults within 500 NM, and 3) status 3 adults within 500 NM. |

| | 150 NM | 250 NM | 500 NM A | 500 NM B |
|-------------------------|---------------------------|--|--|---|
| Txpl Rate | No change | No change | No change | No change |
| WL mortality | No change | No change | No change | No change |
| Post-Txpl mortality | No change | No change | No change | No change |
| Median distance | 144 (decrease) | 200 (no change) | 346 (increase) | 300 (increase) |
| ABO type | No change | A - Tx rate decreased | O – Tx rate increased A - Tx rate decreased | A - Tx rate decreased O - Tx rate increased |
| Regional Differences | 2 – Tx rate decreased | 2 – Tx rate decreased | 1 – Tx rate increased, WL Mort decreased 9 – Tx rate increased | 1 – Tx rate increased 2 – Tx rate decreased 9 – Tx rate increased |
| Status | | 3 – Tx rate increased 4 – Tx rate decreased | 1 – Tx rate increased 2 – Tx rate increased 3 – Tx rate increased 4 – Tx rate decreased | 3 – Tx rate increased 4 – Tx rate decreased |
| OPTIN GNOS No | differential impact based | on: gender, race/ethnicity, | 1A – Tx rate increased urbanicity, insurance stat | 1A – Tx rate increased rus, east/west US |

Table 2: Impact Summary of Changes

Advocates for 150NM opined that "essentially the results are the same" between the 150NM and 250NM in terms of transplant rate, waitlist morality and post-transplant mortality (see Table 2). Furthermore, the Committee members stated that since the travel distance is less for 150NM, there might be cases where the procurement of organs might not have to rely on air transportation. Another Committee member agreed with this statement and opined that 150NM is a "meaningful jump especially for the adult" because the original median distance between donor and transplant hospital "was about 75NM". Another Committee member was concerned that going beyond 150NM would "inadvertently go against the Final Rule because we decrease access because the centers spend so much money on transportation that it limits" their ability to

provide transportation. In essence, the Committee member opined that any larger size distance than 150NM might deter the procurement of organs due to a perceived higher transportation or efficiency cost. Similarly, another Committee member briefly mentioned the point of safety for transplant teams, because such member was concerned of a "reverse lawsuit" should a "plane go down in the next year" over increasing distance.

However, opponents of 150NM stated that this radius is smaller than many DSAs. An example from one of the Committee members was that "150NM is really small....in my area it is ¹/₄ of my DSA". Also, the Committee member stated that it may decrease organ sharing in "certain circumstances, which we have seen with the lungs". Another Committee member stated that "150 miles barely gets us to the next hospital whereas our patients may travel over 1000 miles to come to our hospital". In this Committee member's opinion, 150NM might disadvantage individual programs and not necessarily regions. Several Committee members felt this was not consistent with the Final Rule and the intent of the project.

Opponents for the 250NM radius argued that organ ischemic time will increase with the increase in distance. An example given by a Committee member was that ischemic time at 250NM would be "somewhere between 3 to 5 hours". Furthermore, some Committee members opined that 250NM would increase transportation costs, because transplant hospitals would have to send teams over greater distances. Also, Committee members reiterated that according to Table 2, there were no changes between 150NM and 250NM in terms of transplant rate, waitlist mortality and post-transplant mortality.

Advocates for a 250NM radius argued that although still smaller than some DSAs, it was comparable or larger than many, and thus met the intent of sharing organs more broadly. It also increased the number of transplants for status 3 adult patients. Some in the heart community feel that under the new allocation system, status 3 candidates may be disadvantaged relative to the old allocation system (these patients were 1A and equal to the new status 1 and 2 patients). According to the TSAM modeling consulted during the development of the new heart allocation system, the transplant rate for status 3 was predicted to be ¼ to 1/10 of the status 2 transplant rate. Therefore, 250NM could provide broader sharing for the status 3 patients. In addition, adopting this policy would reconcile current deceased donor lung policy with that of heart policy. Furthermore, an adoption of 250NM would assist in containing the cost of transportation over larger radius sizes.

There was general consensus that the 500NM-A and 500NM-B models could increase cold ischemic time and discards because of the longer distances needed to transport organs. Moreover, most Committee members agreed that the 500NM-A and 500NM-B models would accrue more expenses for Organ Procurement Organizations (OPOs) and transplant hospitals due to a perceived higher cost associated with air transportation. Another Committee member opined that the 500NM-A and 500NM-B does not seem to make a "major difference" on waitlist mortality in their viewpoint based off of the modeling. Furthermore, one Committee member was concerned that going to 500NM "is a big increase in distance to travel for every organ because if the median distance is 350NM then that is a one-hour flight....that is a big difference". Also, other Committee members stated that they have already implemented "broader sharing for the sickest patients" (Status 1 and 2).

However, a few supporters of the 500NM radii argued that the OPTN Final Rule 121.8 required the allocation of organs to be "[distributed] over as broad a geographic area as feasible... and in order of decreasing medical urgency" except for certain medical constraints such as organ ischemia. Furthermore, another Committee member referenced Table 2 and stated that there was no change in the transplant rate, waitlist mortality or post-transplant mortality rates between the different distances. The Committee member opined that in this regard, 500NM would be the

best option based on the data analysis and because it most aligned with OPTN policies for broader sharing.

There was a general divide amongst Committee members as to whether deference to cost and efficiency should drive the decision making process, or whether medical judgement, informed by data, should be the basis for determining nautical mile radius. Some Committee members noted that increasing transportation costs could limit the number of transplants smaller programs would be able to do, versus larger programs. Questions arose as to how much costs would increase as radii increased. One Committee member opined that the total cost of transplanting a patient be evaluated by OPOs and that such information should be mandated to be shared with the OPTN/UNOS. UNOS staff clarified that the OPTN/UNOS Operations and Safety Committee surveyed fifty OPOs, but no definitive cost analysis is available yet. Another Committee member stated, "I get the cost issue, but thenif I was a patient that doesn't matter; I don't care". This Committee member urged other members to not base decisions solely on cost. As such, a small majority of the Committee agreed that decisions should be evidence-based. However, while the Committee should not minimize the issue of cost and efficiency, it is an ongoing challenge for the community to rely on this argument, as there is a dearth of data supporting these claims.

Another Committee member objected and opined that there are in fact different legal and political factors to consider, especially in regards to the OPTN Board of Directors. The Committee member gave an example whereby since the OPTN Board of Directors has already approved lung policy at 250NM, then the Committee might need to consider this. However, other Committee members pushed back on this statement, stating that the Committee has "more data analysis" to make decisions then "previously for the lung policy". Furthermore, other Committee members agreed that they should provide their best recommendation, despite politics that might arise with the OPTN Board of Directors.

The UNOS Director of Policy clarified the OPTN Final Rule Requirements with the Committee. According to the UNOS Director of Policy, there are certain criteria that the OPTN must consider when allocating organs. In one part of the OPTN Final Rule, there is a presumption that the OPTN should be distributing organs as broadly as possible, unless one cannot distribute based on certain issues. For example, there are clinical constraints on the allocation of hearts because on the ischemic time and viability of the organs. As such, UNOS staff advised that the Final Rule placed the burden of proof on the Committee to show why larger radius miles would not be financially feasible, may increase organ discards, or lead to poorer transplant outcomes with broader sharing distances.

Other questions raised were about the accuracy of the results presented in the current data analysis, since collected data for the TSAM simulations were from July 1, 2009 to June 30, 2011. In particular, Committee members noted that Region 3 has had a significant increase in the number of transplant centers since June 30, 2011 and therefore might have higher rates of transplants. The Committee suggested that they examine the nine-month report concerning the modifications to the distribution of deceased donor lungs prior to a formal vote. In doing so, Committee members could evaluate how accurate the TSAM results for deceased donor lungs aligned with nine-month post-implementation results. The Committee agreed to post-pone a formal vote until after the presentation of the deceased donor lung data analysis.

After lengthy discussion with no clear preference between 150nm, 250nm and 500nm, Committee leadership proposed taking an unofficial straw vote prior to adjourning for lunch. The straw poll results are as follows: 500NM-B (0 yes), 500NM-A (1 yes), 250NM (7 yes), 150 NM (8 yes), 1 abstained.

Upon the Committees return and post-presentation of the deceased donor lung data, the Committee members collectively agreed to focus the latter half of the meeting on discussing the justifications for their previous positions in the straw vote. The Committee created an outline of the advantages and disadvantages for each nautical mile radius for ease of comparison. The results from this comparison are in the table below:

| Nautical Mile Radius (NM) | Advantages | Disadvantages | |
|---------------------------|---|--|--|
| 150NM | Perceived increased efficiency (driving versus air transportation) | • Small, almost the size of a DSA, smaller in some cases | |
| 250NM | Potentially better post-transplant outcomes Increased number of transplants for status 3 adult patients (large number of patients, better post-transplant outcomes, previously 1As) Increased broader sharing | Total ischemic time increased due to the dual use of air and ground transportation | |
| 500NM- A & 500NM-B | Is the broadest sharing model Pediatric hearts already travel these distances | Total ischemic time increased due to the use of air and ground transportation Increased perceived cost and cold ischemic time (CIT) No apparent benefit to patients (outcomes) | |

Table 3: Nautical Mile Comparison

Other points of discussion included ischemic time and distance for pediatrics and adults. Committee members pointed out that major driving factors behind the data analysis are acceptance practices. For example, transplant hospitals might be less willing to accept an organ if said organ was procured at a distance that would increase ischemic time to that of four or more hours.

Also, some Committee members felt there needed to be further analysis on the impact that the different radius miles would have on individual programs and transplant hospitals. Some Committee members expressed concerns that certain programs could be disadvantaged more than others, and that some regions could experience difficulties in maintaining their current number of transplants.

At the end of discussion, The Committee initiated a formal vote. The results of the formal vote are as follows: 500NM-B (0 yes), 500NM-A (0 yes), 250NM (10 yes), 150NM (7 yes).

In conclusion, the Committee formally voted on three out of the four action items placed on the agenda. The first formal vote was regarding the distance to replace DSA as first unit of distribution. The outcome was 250NM (10 yes) and 150NM (7 yes).

The second formal vote was over the multi-organ policy. The Committee unanimously voted to replace the multi-organ policy containing DSA with 250NM.

The third formal vote was the exception to allocation for sensitized heart candidates. The Committee voted unanimously for Option 1: Strike the policy.

The Committee did not vote on the fourth action item on the agenda and will plan to do so at a later time.

Next steps

The Committee's formal vote on the adoption of 250NM as the distance to replace DSA as first unit of distribution will be presented to the OPTN Board of Directors for consideration.

2. Modifications to the Adult Heart Allocation System

Implemented October 18, 2018. Brief update on the release of new adult heart allocation and preliminary counts on the number of initial justification forms and exceptions by adult heart status.

Data summary

The data analyzed compared the results of Phase 1 of the adult heart allocation system. In October 2018, there were sixty-three active adult candidates that did not have a form submitted when the system went live. These sixty-three adult candidates were converted to a status 6 in the system. Overall, there were 2,611 active candidates that were converted to a new adult heart status.

The rest of the data analysis Focused on exceptions requests.

Summary of discussion

There was general agreement amongst Committee members that regional board's crossreviewing cases approved the majority of cases. Committee members noted that those cases that the regional boards did not approve had valid reasons for rejection.

The Committee has for clarification was to which regions were reviewing whom. The Committee initially believed that the OPTN/UNOS randomly assigned regions to review each other over the course of one year, however the Committee presented a table that showed otherwise. It was determined that in actuality, each region's review board is initially paired based on size and volume. As such, there was general concern on regional practices affecting the review of exception cases. There is considerable concern that the culture of a region can affect the determination of exception cases, whereas one region might be stricter in evaluating cases then another. Furthermore, there is concern that the one-year length of time for regions to review each other is too long, and could negatively affect the outcomes for exception cases.

Lastly, the Committee members were shown a tool on the OPTN website where they could find the most current data for waiting lists, distribution of adult and pediatric status groups and other organ transplant metrics. Committee members discussed how to select various metrics and data using the online tool. The Committee was given a demonstration on how to locate and utilize the toll effectively.

Next steps

The Heart Subcommittee may opt to take up a project solely focusing on the extension policy language across all criteria and to correct any unintended issues with the status 4 inotrope policy language. The Heart Subcommittee also desires to look further at the timeline for regional rotations in order to assess if one year rotational schedules are too long.

3. Modifications to the Distribution of Deceased Donor Lungs

On November 24, 2017 an emergency action change to lung allocation policy removed the donor service area level of allocation for deceased donor lungs (first unit of allocation) and replaced it with a 250 nautical mile circle around the donor hospital. The primary goal of the policy was to address concerns over compliance with the final rule as a result of a lawsuit and subsequent emergency action taken by the OPTN/UNOS Executive Committee. UNOS staff presented the nine-month monitoring report.

Data summary

While statistically significant differences were found between the pre to post era on some metrics, clinical relevance still needs to be established. There was a statistically significant increase in the match LAS at listing in the post era. When analyzing additions to the waiting list, there were not statistically significant differences between pre and post era candidates' diagnosis group and deaths per 100 patient years while waiting overall and by each diagnosis group. There was a statistically significant decrease in the death rate for candidates in the 60-70 LAS group.

The transplant cohorts do not differ across eras with respect to diagnosis group, procedure type, donor type, or ABO. Some OPTN regions saw a decrease in the number of transplants between pre and post era; however, five saw an increase. The distribution of LAS at transplant for the recipient population has changed- there has been an increase in the mean match LAS at transplant. This is considered an expected change as it was predicted that more high LAS candidates would receive transplants. The mean match LAS at transplant still varies across OPTN region. The distance that lungs travel (distance between donor hospital and transplant center) has changed such that there was an increase in the median distance. There has also been a decrease in the number of local lung transplants and increase in the number of regional and national lung transplants. The mean time between first electronic offer and cross clamp and the mean ischemic time have increased in the post era. The transplant rate has not significantly changed when examined by diagnosis group; however, LAS group 40-50 did see a statistically significant decrease in the transplant rate.

The last metric examined was deceased donor utilization. The majority of OPOs recovered equal or more lungs that were eventually transplanted in the post era compared the pre era. The discard rate for lungs remained low; notably, the OPTN regional variability of discard rate remains present in both eras. The same may be said for the utilization rate of lungs. Generally, the utilization rate for lungs is lower than other organs. While it remains low, there is clear variability across the OPTN regions. There has been an increase in the use of EVLP; however, this is presumably not entirely due to the policy change, but also due to the progression of this technology.

Summary of discussion

Committee members questioned if there was a change in transplant rates between single and double lung transplants. There has not been a change in the number of single vs double lung transplants.

A question that was raised is if the match LAS distribution across each region is similar or variable. Though not in the slide deck, the report does show significant variability between each OPTN region.

Discussion was also had regarding the clinical significance of increasing mean LAS scores. It was noted by the Committee that though the data points to statistical significance, the data may not be necessarily clinically significant. However, it was noted that a difference of two point changes in the LAS is considered clinically significant during data analysis.

A common theme discussed by the Committee were the limitations of the data analysis. Several of these limitations were discussed by the Committee, including small sample sizes or cohorts, and the short time-frame in which data has been collected. The Committee discussed several ways this could impact the data analysis and the relevance of statistical significance.

A suggestion was made to the Committee that with an increase in the number of Donor after Cardiac Death (DCD), it might be beneficial for the Committee to consider tracking DCD donor outcomes for future analysis.

The Committee also discussed favorably the effects that the new lung allocation policy has had on region nine and two in terms of the number of DCD transplants. There was general agreement that the TSAM was able to predict regional decreases and increases in the number of DCD transplants. Furthermore, the TSAM was able to accurately predict the distance that transplanted lungs traveled.

However, Committee members pointed out that one aspect TSAM is not able to accurately predict is modeling behavior and the ability for people to change their behavior. For example, the TSAM did not predict that high volume transplant centers would see decreases in center volume. One Committee member suggested that specific centers should be looked at in order to see which centers are experiencing more lung transplants and volume increases, however UNOS staff members clarified that they cannot do so because of issues surrounding confidentiality.

Many Committee members voiced concern that the delay in time could become worse and that the Committee should focus on increasing efficiency. However, this was postulated as a potential Committee project in the future.

One Committee member considered the cold and warm ischemic time as irrelevant for lungs, due to the fact that the mean ischemic time is well below the seven or eight hour mark. However, this is different for heart transplants, which are more time specific. It was noted that there is no consensus in literature on ischemic time, and therefore it might be beneficial to not increase nautical miles for hearts.

Clarification was made regarding the amount of foreign transplants occurring, specifically to Canada. There was concern that lungs are being exported at higher numbers, however only two have been exported in the post-implementation.

Questions were raised regarding how OPOs report "recovered for the purpose of transplant" and whether dry runs are reported by OPOs as "recovered for the purpose of transplant". Some Committee members state that OPOs mark an organ as "recovered" even if a transplant team views an organ but does not procure the organ. This means that even if there is an "intent" for an organ, then the organ was marked in the discard rate (including dry runs, or teams that do not show up). However, there is general debate that "recovered for the purpose of transplant" only means organs that were procured. The Committee agrees that there needs to be a clarification on the term "recovered for the purpose of transplant" with OPOs to make sure that data is being recorded appropriately.

There was an overall consensus that evaluating this data prior to having a formal vote on the elimination of DSAs for heart allocation was informative.

Next steps

The nine-month analysis report will be published on the OPTN website. The next analysis report will examine the one-year post implementation outcomes.

4. Collection of Ex Vivo Lung Perfusion (EVLP) Data on the Deceased Donor Registration form (DDR) and Transplant Recipient Registration form (TRR)

On March 31, 2015 fields were added to the deceased donor registration (DDR) to indicate whether a donor lung had machine perfusion intended or performed. The first national reporting was reviewed by the OPTN Thoracic Transplantation Committee in the Fall of 2017. This report will contain additional analyses of primary graft dysfunction and 1-year patient survival for lungs reported as having perfusion intended or performed on the DDR. A crosswalk will also been done between the perfusion fields added to the transplant recipient registration (TRR) on February 28, 2018 and those on the DDR. UNOS staff summarized the few months of data that has been collected on the TRR.

Data summary

The majority of lungs recovered for transplant do not indicate machine perfusion intended or performed prior to transplant. Of the lungs that did indicate machine perfusion intended or performed prior to transplant, a little over half of those were transplanted. In examination of this by OPO, it is clear that there is variation across OPO. The OPOs with higher volumes of lungs with machine perfusion intended or performed prior to transplant were not localized to one area of the United States nor were they necessarily OPOs with high volumes of lungs recovered.

Early outcomes with a small sample size indicate that there is not a statistically significant difference in primary graft dysfunction grade between those with perfusion intended or performed and those without. Similarly, there was not a statistically significant difference in the 1-year patient survival for recipients of perfused lungs verses not perfused lungs.

New fields were added to the TRR on February 28, 2018 collecting whether the lungs were perfused prior to transplant. The data reported on the DDR was compared to the data collected on the TRR for a 4 month cohort. There were clear inconsistencies between reporting on each form. Additional data elements on the TRR show that the majority of lungs are perfused by the transplant center and the majority were perfused at the recovery site.

Summary of discussion

Overall, there was notable concern regarding the inconsistencies and accuracy of the data being collected. There is a significant lack of data being reported due to the TRR form allowing for recorded responses to be marked as "unknown", "N/A", "not done" or "missing". The Committee is concerned that this allows for centers to "opt-out" of recording certain data points. There is also great concern that over half of the data is not being recorded, and therefore the data results may be inaccurate.

The Committee did acknowledge that the EVLP data analysis should be made publically available for patients and external stakeholders, however due to raised concerns regarding data accuracy, it was decided by the Committee to not post the data publically at this time.

5. Collection of Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates

Due to time constraints, this data was not presented to the Committee for consideration.

Upcoming Meetings

• November 29, 2018 : Full Thoracic Committee Meeting