

**OPTN/UNOS Policy Oversight Committee  
Report to the Board of Directors  
June 28-29, 2011  
Richmond, Virginia**

**Summary**

**I. Action Items for Board Consideration**

- None

**II. Other Significant Items**

- The Committee reviewed 96 committee projects and will forward recommendations to the Executive Committee. (Item 1, Page 3)
- The Committee discussed multi-organ allocation policies and will be requesting feedback from the Board on a path forward. (Item 2, Page 4)
- The Committee reviewed 14 proposals that were distributed for public comment on. (Items 4-17, Pages 6-16)

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**Stuart C. Sweet, MD, PhD, Chair**

*This report represents the deliberations and recommendations of the Policy Oversight Committee during its meeting on March 29, 2011, in Chicago, Illinois.*

1. Committee Project Prioritization

*Background Information*

Over the past several years, the leadership of the OPTN has recognized the need to look at the work of the committees and the priorities of the OPTN. The Chrysalis project is underway and will make the computer systems more efficient and effective at programming changes. However, even with a new computer system in place it will not possible to implement every project or idea that gets proposed by the various committees. What is being proposed is a rational process for reviewing projects early on and trying to decide what projects have the highest value and the most impact on patients and on transplant centers. This is especially important in order to prevent a committee from spending time and resources on a project that might not be a high priority or does not fit into the strategic goals of the OPTN. Therefore, committee liaisons and chairs were asked to submit a project form (**Exhibit A**) to help guide the decision-making process. The POC will review the projects and forward their recommendations to the Executive Committee.

*Review and Prioritization Methodology*

There were 96 committee project forms submitted for review by the POC. (**Exhibit B**). The projects were grouped according to key goal<sup>1</sup> prior to the meeting. Additionally, within each key area the projects were listed according to the estimated liaison time required for the project and whether programming was required. A draft scorecard (**Exhibit C**) was created prior to the meeting and used to score each project. It was noted that because this is the first run at this new process, the scorecard will need to be modified for future reviews. The methodology used for the review was an initial screen of the projects. Each project was categorized as either yes, no, or maybe according to the following criteria:

- Yes (46) - Projects that clearly fit with OPTN goals and have consensus for high priority. These will be scored as 1 (aligns with a goal but needs work or has a small impact) or 2 (this can move forward as one of the strategic goals).
- No (8) – Projects without clear alignment to an OPTN goal, unlikely to be completed or has a low cost/benefit. The POC will provide specific feedback to committee if a project is listed in this category
- Maybe (30) – Everything else. These will be discussed in greater detail and scored.  
*Note: Number in parenthesis indicates number of projects listed in that category.*

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<sup>1</sup> Key Goals: Increase the number of transplants, increase access to transplants, improve post-transplant survival, promote transplant patient safety, and promote living donor safety.

In addition to the three categories listed, there were several items already discussed during the review of public comment items. Additionally, there were three Transplant Administrators Committee projects that are considered UNOS private activities.

Following the initial review, the committee went through the “maybe” projects in order to assign a score and have further discussions. A complete list of the project scores can be found in **Exhibit D**. Following the meeting, UNOS staff summarized the scoring and comments and distributed the list to the POC members for final approval. This list will be provided to the members of the Executive Committee in preparation for their meeting in June 2011.

#### *Additional Discussion*

There was a question raised about whether the individual committees ranked their own projects. It was noted that this was not something the committees were asked to do for this initial review but that feedback would be used in preparation for the reviews next year.

It was noted that some of the projects proposed by non organ-specific committees were items which organ-specific committees should be consulted. It was noted that most of the documentation used for committee work contains a reference to collaborative efforts, including other committees and relevant professional organizations.

It was noted that some of the projects listed were close to completion but still required liaison time. Additionally, just because a project has been started does not mean it necessarily has to be completed. As the organization moves forward, decisions might need to be made about how much time and resources are used on a project that keeps getting pushback or fails to progress.

One final issue discussed was the need for the organization to make decisions about what needs to be in policy and what can be considered operational. For example, how to deal with a tie in multi-organ allocation policy? If there is a scenario that happens once every five years, does the organization need to invest the time and resources to prepare a proposal, gather the data to support it, and then program it? One thought was to develop a threshold for that process and then get the Board and HRSA to acknowledge that there will be situations where the decision is an operational decision and does not need to be covered by policy. If there is clear documentation of the intent of the committee about how something should be handled and it does not have a broad impact, then changing the policy to cover every possible situation may not that make sense or be the best use of limited resources.

## 2. Multi-Organ Allocation Subcommittee Report

Dr. Stuart Sweet gave the Committee a brief overview of the discussions from the two subcommittee conference calls. (**Exhibit E**). Additional information about the conference calls can be found in **Exhibit F**. Some of the issues discussed during the conference calls included:

- Developing a framework to review the policies
- Voluntary sharing of the second organ
- Payback issues
- Minimum listing criteria
- Balancing equity and utility

### *Full Committee Discussion*

The Committee agreed that a good first step would be to look at the current policies to see if there are ambiguities and if so, determine how to fix them. Additionally, determine if there are common ethical principles within those policies that should apply to all. For example, in the heart/lung policy, the intent is to prevent a heart/lung candidate from being allocated a heart before a heart candidate with higher wait list mortality. An important principle is to try to balance the policy so that the sickest patients do not lose an opportunity for an organ while at the same time not causing heart/lung candidates to die waiting for two organs. This includes determining if any subgroup in the existing policies is disenfranchised and consider modifying any such policy in order to reduce it. It was noted that creating a mechanism to reduce the disenfranchisement of subsets within the population will become more complex because everything becomes more organ-specific. Once we have established this ethical framework we will require input from all the organ-specific committees and review each existing policy to ensure that those ethical principles are met.

The Committee discussed the issue of mandatory sharing only if the donor is within the local DSA. Given the direction the OPTN is going with broader sharing for the sickest patients, should this still apply or should the sharing be expanded to be more consistent with the other policies? It was noted that the recommended sharing issue does not just apply to organs going to the sicker patients outside the region, but also to candidates that are highly-sensitized and get a zero mismatch offer. An example given was if a highly sensitized patient has a kidney/pancreas offer where the outside DSA sends just the kidney and not the pancreas leaving that person with the chance of never getting a pancreas offer because they are so sensitized.

### *Balancing Utility and Equity*

The Committee noted that because of the growth of the waitlist it might be time to change the way we think about multi-organ allocation. For example, it is difficult to determine if doing a liver/kidney transplant is the best use of organs versus doing an isolated liver and an isolated kidney and helping two candidates. It was noted that there is mortality on the kidney list and mortality on the liver list, and there are always going to be the arguments about who are the sickest patients and although there is no right answer, there just needs to be some direction provided. It was noted that we still have to consider sickest and lifesaving, but we can make sure the policies address equity since it is not clearly incorporated into our current policies. There needs to be a balance between saving lives and having the best outcomes, against giving patients a reasonable chance of getting a transplant.

### *Minimum Listing Criteria*

The Committee agreed that it is important to create minimum listing criteria will be important as we move forward. It will be a major undertaking as shown by several years of work done developing minimum listing criteria for liver/kidney transplants. It was noted that if there are going to be minimum listing criteria for getting a kidney with a liver, the criteria should be consistent to receive a liver with a kidney, or a liver with a heart.

### *Path Forward*

Dr. Sweet will present this information to the Board of Directors during its June 28-29, 2011 meeting in order to get feedback on the path forward. The POC recommends:

- The POC take the leadership role and recommends the formation of a joint subcommittee with members of the organ specific committees.
- The subcommittee will establish a set of goals that will be used to frame committee discussions.
- The subcommittee will identify the ethical principles and framework for the review of multi-organ allocation policies.
- The subcommittee will oversee the development of minimum listing criteria for all organs involved in a multi-organ transplant.

### 3. Memo from the Pediatric Transplantation Committee

The Committee reviewed a memo from the Pediatric Transplantation Committee (***Exhibit G***) seeking input on changes to the bylaws that would address the need for pediatric transplant experience in order to be approved to become the primary physician or surgeon in a pediatric transplant center. The bylaws currently have no requirements for pediatric programs. This issue was brought to the Pediatric Transplantation Committee by the MPSC because of concerns that a surgeon with no pediatric experience submitted an application to serve as the surgical director for a pediatric program.

The Committee noted that creating a separate set of criteria for pediatric centers would not be a cost-effective solution to this problem; instead the Committee should explore the possibility of adding some specific language to the existing criteria for primary physician and surgeon. It was noted that CMS currently has specific requirements for pediatric transplant programs so whatever is developed should align with those requirements. The POC agreed to provide the following feedback to the Pediatric Transplantation Committee:

- This issue is important and should be addressed with the following stipulations:
  - A separate set of requirements in the bylaws is not required and consideration should be given to the current CMS requirements for pediatric transplant programs.
  - The Pediatric Transplantation Committee and the MPSC should form a joint work group to work on this issue.
  - The POC should be updated on the progress of the work so that periodic input can be provided.

### **Review of Proposals Circulated for Public Comment, Spring 2011 (*Scores Provided in Exhibit H*)**

#### 4. Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization. (*MPSC and OPO Committee*)

Summary of proposal: The Organ Procurement Organization (OPO) Committee and the Membership and Professional Standards Committee (MPSC) propose the use of a statistical model to analyze OPO performance. This model utilizes a comparison of observed (actual) to expected organs transplanted per donor (yield) based upon donor specific characteristics in each Donation Service Area. The model will be used in aggregate (for all organs) in addition to organ specific performance measures,

and predicts how many organs would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristics. The MPSC will use the model to monitor OPO performance, similar to existing practices for monitoring transplant program performance. Through this approach, the MPSC will identify opportunities for improvement at OPOs whose observed organ yield falls below expected levels by more than a threshold. The bylaw proposal provides information regarding the model's intended use by the MSPC as well as the threshold that will result in MPSC inquiry.

The POC had some concerns about how transplant centers impact OPO performance and whether the transplant center component was considered. It was noted that the transplant center effect is something that can be identified as part of the survey tool that will go out when an OPO gets flagged. The survey tool will allow OPOs the opportunity to inform the MPSC of situations that impact their performance that are outside their control, such as issues related to the transplant centers.

Another area of concern is the cost of a peer visit, especially if there is an issue with the transplant center(s) identified that contributed to the OPO getting flagged. There needs to be a mechanism for getting the transplant center or centers within the DSA involved in the initial discussions and, if necessary, some sort of cost sharing between the transplant center(s) and OPOs if a peer visit is deemed necessary by the MPSC. The POC noted that it is clear that the relationship between OPOs and transplant centers can influence outcomes and performance for both organizations and questioned whether OPO performance comes up during the discussions of transplant center performance. It was noted that the MPSC takes that into consideration when reviewing and discussing further action against transplant centers, keeping in mind the need to maintain confidential medical peer review protections.

A Committee member noted that CMS (Center for Medicare and Medicaid Services) has developed separate performance measures for the OPOs located in Hawaii and Puerto Rico and wondered if there was consideration given to the unique geographic and infrastructure issues of those areas. It was noted that the MPSC discussed the issue but was unable to model it because of the low volume; however those factors would be considered by the MPSC if an OPO is flagged. It was also noted that the committee has not identified a process for the reviews and will be discussing this in the coming months as this proposal moves forward.

There was some concern about how this proposal could potentially impact the number of organs transplanted. This included issues such as the utilization of DCD organs, transplant/acceptance rates, marginal donors, and other factors that could have an impact on OPO performance. While there is a reasonable risk adjustment included in the models, there might be an overall reduction in the number of organs transplanted, particularly if the OPOs believe they do not have control over the utilization of the organs being offered. For example, the recovery utilization of a pancreas is an issue of having a pancreas center within your OPO because allocating a pancreas outside the DSA is much more difficult because of the increased cold ischemia time. Additionally, as the Liver and Intestinal Organ Transplantation Committee works toward broader sharing, there is concern about OPOs that perform well sharing organs with underperforming OPOs. The POC provided these additional comments:

- It would be informative to look at the first set of OPOs that are flagged and evaluate important processes that need to be in place.
- There are metrics such as potential donors, donor population, and conversion rates that should be included in any flagging methodology.

- It is important to note that although OPOs might not get flagged with this new methodology, it is important to continue to work on performance improvement and strive to more donors and better donor numbers.

The POC agreed that determining an objective way of assessing OPO performance is an important step forward and voted to support the proposal and submit its comments for consideration by the MPSC. Committee vote: 14 in favor, 0 opposed, and 0 abstentions.

5. Proposal for Improved Imaging Criteria for HCC Exceptions (*Liver and Intestinal Organ Transplantation Committee*)

Summary of proposal: Patients awaiting a liver transplant who are diagnosed with hepatocellular carcinoma (HCC) are eligible for additional priority through MELD/PELD exceptions. Under this proposal, HCC lesions would be classified more precisely according to newly-defined imaging criteria, with only Class 5 potentially eligible for automatic upgrades.

Currently, HCC exceptions are based on diagnostic criteria that rely on imaging characteristics rather than liver biopsy. The attendees of a multi-disciplinary HCC Consensus Conference held November 2008 made specific recommendations regarding the appropriate imaging criteria to properly determine HCC staging. The Committee is proposing to incorporate these recommendations into Policy 3.6.4.4. A survey of all U.S. liver transplant programs in October 2010 indicated strong support for these changes.

A Committee member noted that this is a good proposal that addresses some of the issues with many patients listed nationally with HCC exceptions; and because these candidates get so much priority it was felt that more stringent standards needed to be adopted. Additionally, since this does not require programming it should be a low cost solution. The cost to members would be minimal since most centers already have a multi-disciplinary team with radiologists that review the imaging.

The Patient Affairs Committee (PAC) discussed this proposal at their meeting on March 28<sup>th</sup>, 2011 and while they agreed this change would lead to more appropriate allocation of livers; they did have the following concerns:

- Insurance coverage for repeat imaging studies and radiology reviews. It was noted that there should not be any additional costs to patients because most transplant centers are already doing this.
- Failure to get exception points when patients really do have HCC. It was noted that if a lesion is indeterminate, the physicians following the patients will probably have new imaging studies done in 3 months so this policy change will not have an impact on patient care.
- There was concern about the lack of documentation in the proposal about the national conference. It was noted that the imaging recommendations were included in the published recommendations from the HCC consensus conference in *Liver Transplantation* in 2010.
- No plan to follow the patients that fail to meet new criteria but would have met old criteria. It was noted that candidates who are already listed with an HCC exceptions will keep their points. Additionally, this proposal does not change the criteria; it just requires more specific imaging information.

The Committee supported the proposal by a vote of 12 in favor, 0 opposed, and 1 abstention.

6. Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates (*Liver and Intestinal Organ Transplantation Committee*)

Summary of proposal: The proposal is intended to reduce the death rate on the waiting list for adult combined liver-intestine candidates by providing broader access to donor organs. Waiting list death rates in adult candidates awaiting a combined liver-intestine transplant are nearly three times higher than those waiting for a liver alone. This is a numerically small patient population with high waiting list mortality rates due to the need for two organs and donor organ size constraints.

It was noted that the number of adult liver-intestine candidates was too small to perform allocation modeling or analyze the potential impact on waitlist mortality. This proposal will greatly benefit this patient population because of their high waitlist mortality and allow for broader sharing of liver-intestines for adults; something that was done for pediatrics a few years ago. Although there are approximately 70 adult liver-intestine candidates on the waiting list, this is a good example of a policy that will have huge impact on a small set of patients. However, there was some concern from the PAC about the potential for this change to take livers away from candidates who are waiting for livers only. It was noted that the Committee proposed that offers be made to liver only candidates with MELD of 30 and above before going out to liver-intestine candidates in order to allow the sicker liver candidates to maintain priority over these patients. Additionally, it was noted that the proposal will have a limited effect on pancreas allocation but not enough to oppose the proposal.

The Committee supported the proposal by a vote of 13 in favor, 0 opposed, and 1 abstention.

7. Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation (*Liver and Intestinal Organ Transplantation Committee*)

Summary of proposal: This committee-sponsored AAS (CAS) is intended to increase the number of transplants and reduce waiting list deaths by transplanting the right lobe into an adult patient and the remaining lobe/segment into a second candidate. The CAS will potentially reduce waiting times for liver candidates overall, because the liver pool would be expanded by splitting livers that otherwise would not be split. In November 2010, the Board of Directors approved two alternative allocation systems (AAS) to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). At that time, the Board asked that the Liver Committee consider developing a committee-sponsored AAS (CAS) that would allow other Regions and OPOs to participate in a split liver AAS. This proposed CAS is based on the approved Region 2 and One Legacy AASs, but will provide one standard model for all participants to follow. In summary, if an adult candidate is offered a liver through the standard policy or an approved-AAS (i.e., via the match run) who has been determined to be suitable for a segmental liver transplant (known as the index patient), the candidate's transplant center may transplant the right lobe into the index patient. The center may then transplant the left lobe/segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable), in order of the match run.

It was noted that this proposal differs from the two split liver AAS proposals approved by the Board of Directors in November 2010. This current proposal includes adults, whereas the Region 2 and One Legacy proposals were more focused on right trisegmental and left lateral segment splits. There was some concern about the outcomes for adult-to-adult splits although the proposal mentions the single center studies that are pioneering these techniques show results to be excellent. The assumption is that these are centers of excellence and that the increased use of splits in centers that are not as experienced in the techniques could cause an increase in morbidity and/or mortality for the recipients of split liver grafts. It was noted that following up on outcomes will be very important

because if there is an increase in the number of centers performing split liver transplants the results might not be as good as the centers with more experience. Additionally, exploring potential allocation priority for the candidates who accept split livers might be worth considering because this is one of the few proposals where there is no direct benefit to the initial recipient in accepting a split liver as opposed to a whole liver. Certainly there is a benefit to the system but recipients need to be assured that there will be no increase in morbidity or mortality to them. The Liver and Intestinal Organ Transplantation Committee addressed the concerns about the risks to the index patient, including a discussion about possibly requiring a separate consent form. However, it was determined that since a different consent for DCD donors is not required, it should be up to the individual transplant centers to inform candidates about the potential risks of receiving a split liver.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

8. Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability (*Thoracic Organ Transplantation Committee*)

Summary of proposal: The Thoracic Organ Transplantation Committee proposes the addition of CT scan to Policy 3.7.12.4 (Desirable Information for Lung Offers). An OPO is encouraged to provide this information if it is requested to do so by a transplant program. The proposed policy does not require a transplant program to request a CT scan.

Deceased donor lung or lungs may have contusions or infiltrates or malignant nodules, which may not be visible in a chest x-radiation (CXR). A computed tomography (CT) scan can identify these contusions, preventing the transplant of a damaged lung. The CT scan can also identify nodules which may be malignant, preventing the transmission of cancer or tumors to the recipient.

The only concern with this proposal was the potential for the CT scan to be billed to a patient if the patient is not declared brain dead. It was noted that the OPOs have a way of tracking charges prior to death and frequently there are procedures or tests that are performed prior to death. When the OPO Committee discussed and voted to support this proposal, it discussed the need to review Policy 2 because there might need to be some cross-referencing so the language will be consistent.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

9. Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability (*Thoracic Organ Transplantation Committee*)

The Thoracic Organ Transplantation Committee proposes that Policy 3.7.6.3.2 require transplant programs to update in no less than 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for candidates whose scores are 50 or higher. The proposal would require transplant programs to update candidate data for high-LAS candidates whenever changes occur to assisted ventilation, supplemental oxygen, or current PCO<sub>2</sub>.

Policy 3.7.6.3.2 requires a transplant program to update its candidates' clinical data in UNet<sup>SM</sup> values every six months. A candidate whose lung allocation score is 50 or higher is likely receiving therapeutic interventions that may decrease her or his score, but does not currently require more frequent updates if the candidate's health improves.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

10. Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time (*Thoracic Organ Transplantation Committee*)

Summary of Proposal: On November 9, 2010, the OPTN/UNOS Board of Directors approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. These candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates do not qualify for Status 1A by other existing criteria, they must be downgraded; and, they may be Status 1B.

Recent availability of a portable driver has allowed some candidates with TAHs to await a heart transplant as outpatients. Prior to the availability of this new instrument, all candidates with TAHs remained inpatients. Policy allows all inpatient TAH candidates to be classified as Status 1A for 14 day periods; however, policy previously prevented outpatient candidates implanted with TAHs to be listed as Status 1A unless they qualified by other criteria. There are no data to suggest that the medical urgency of an inpatient candidate with a TAH implant is different from an outpatient candidate with a TAH implant.

The question was raised about whether there had been discussion about bringing parity across the system in regards to the inpatient time of the VADs and TAH. It was noted that one of the arguments is whether such parity should be based on medical evidence and not just ethical issues. For example, if it turns out that the TAH patients are sicker and there is medical reason why they should have some level of prioritization over VADs, then that should be taken into account. It was noted that the problem is that data is hard to come by because there are so few patients and the data available is contained within an ongoing study that has not been published yet.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

11. Proposal to Improve the Reporting of Living Donor Status (*Living Donor Committee*)

The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. The transplant community must collectively improve patient information on the LDF form to allow for meaningful analyses to objectively study the short-term effects of living donation. Data on living donors who donated in 2006 through 2008 demonstrate that many programs do not report the status of their living donors at required reporting intervals. Under this proposal, transplant programs would be required to accurately report if the living donor is alive or dead at the required post operative reporting periods (6, 12 and 24 months). Follow-up information on donors is especially important in the current climate where the public and the media seek data on the safety of living donation. Without accurate and comprehensive living donor follow-up data, it will not be possible to answer questions and address concerns.

While it acknowledged that this proposal is the first step towards getting more information about the status of living donors, the POC had the following concerns:

- There are currently short and long term data from a variety of sources that show the risk of living donation is minimal. Additionally, information about deaths can be obtained from the Social Security Death Master File.

- The proposal only requires centers to report whether the living donor is alive or dead which will not provide a great deal of information about the risk of living donation. What is needed are data that will be helpful in looking at predictive models of negative outcomes for living donors, not just whether they are alive or dead. This includes:
  - Data to ensure care of the living donor and to develop predictive information about donors that are at higher risk. Data should include targeted populations and sub-populations that are at higher risks such as certain minorities and ethnic populations with an increased risk for hypertension and diabetes. Are there predictors that can be identified in the immediate post-operative period or in the first six months after living donation that are predictors of poor outcomes that can be used to develop those target populations?
  - A Committee member noted that while this issue is moving in the right direction, it is important to collect data that can be used for risk analysis, especially if the procuring centers can be the ones collecting the data since they are evaluating the potential donor to assess their suitability for transplant.
- There was a question raised about the time points identified in the proposal and it was noted that the 6, 12, and 24 months intervals are what is currently required in policy.
- It was noted that data submission means there are data submitted on the OPTN forms and does not mean that a care provider is identified or that the living donors are actually being followed. It is very important to make a distinction between gathering data and delivering care. The focus of what the OPTN should try to accomplish is ensuring that the living donors have ongoing care. And with that ongoing care is the partnership for communicating information back to the OPTN and unfortunately some of the policies that are put in place do not guarantee the first part happens.

HRSA noted that living donor follow up is a very important issue and issues with living donor follow up are not going to be resolved with this item or any other single item. There are many areas that need to be addressed and it is important for POC to note in its comments that if analytically this is the wrong way to improve the data collection problem. OPTN members are required to report information at the established time intervals; however, if the data that is being reported is not improving living donor safety then it would be helpful to provide suggestions about alternative ways to improve that data collection.

One committee member opined that what the OPTN should really do is look at practices that increase the risk of donation within individual transplant centers in order to protect living donors. The OPTN has only been involved with the regulation of living donation for a few years now and data collection is a way to ensure that their membership is providing care in a way that is in the best interest of donors. The question is whether the data being collected helps accurately determine if members are practicing living donation within the standards that we set as an organization? The hope is that data collection is an effective proxy for assurance that the patient is getting good follow up care. That is the best that the OPTN can accomplish but the question remains whether requiring information about whether the patient is alive or dead really improves living donor follow up.

The POC agreed to provide the following feedback to the Living Donor Committee:

- There is agreement that the data being collected on living donors needs to be improved. Incomplete forms, donors lost to follow up, and the low completion rate on living donor forms will not allow for accurate outcome predictions for living donors but it is unclear how this proposal will help with the problem.
- Evaluate the current reporting requirements and make changes that will improve the long-term care for the living donor, including a mechanism where data can be returned to the OPTN from the care providers.
- It was noted that the OPTN cannot mandate patient care; however it does require data collection. If data collection is considered a proxy for care then it raises some concerns because if the quality of data is poor it might imply poor quality of care.
- It was also noted that there is policy in place that requires reporting of living donor deaths within 72 hours so it was unclear how this new proposal would add useful information.
- The POC supports the concept of ensuring adequate living donor follow up and data collection; however, the proposal does not clearly address those issues. Knowing whether the living donor is alive or dead does not provide information about whether they are actually being followed or provide data that will add to the outcomes predictors. The POC recommends that the Living Donor Committee review the data reporting requirements and try to identify data elements that are likely to be predictive of long-term outcomes. These elements should be revised first before adding requirements to existing policy that are not clearly beneficial in terms of the long-term goals.

The Committee *did not* support the proposal by a vote of 0 in favor, 13 opposed, and 1 abstention.

12. Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials (*Living Donor Committee*)

Summary of proposal: The majority of living donor organs recovered for transplant are not shipped or transported outside the recovery center, and therefore would not be affected by this proposal. However, the packaging and shipping of living donor organs is increasing, especially as “kidney paired” donation increases throughout the country.

Changes to the policies for the packaging and shipping of deceased donor organs, vessels, and tissue typing materials were approved by the OPTN/UNOS Board in November 2010, and took effect in January 2011. The implementation of these new policies has created a situation where the rules for packaging, labeling and shipping deceased donor organs are more stringent than policies for the packaging, labeling and shipping of living donor organs. In response, this proposal would update living donor policy to more closely align with recent changes to the policy requirements for the packaging, labeling and shipment of deceased donor organs, vessels and tissue typing materials. The proposal also clarifies procedures when the living donor organ is not packaged, shipped or transported. The Committee anticipates both transplant centers and Organ Procurement Organizations (OPOs) would benefit from the standardization of packaging and shipping requirements for all organs. The Committee further expects that applying the existing requirements for the packaging and shipping of deceased donor organs to living donor organs, vessels and tissue typing materials will

increase the safety of living donor organs that are packaged and transported outside the recovery facility.

The proposal would not preclude transplant centers from entering into an agreement with an OPO to coordinate the packaging and shipping of living donor organs, vessels and tissue typing materials.

There was a question raised about whether this applies when the donation occurs at the adult hospital and the organ is transported over to the children's hospital. It was noted that if it is on the same campus and the OPO is not involved, then only the time out rule would apply.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

13. Proposal to Require Confirmatory Subtyping of Non-A<sub>1</sub> and Non-A<sub>1</sub>B Donors (*Operations and Safety Committee*)

Summary of proposal: This proposal would require confirmatory subtype testing of blood group A and AB deceased or living donors when subtyping is used for the placement of organs, and the donor is identified to be subtype non-A<sub>1</sub> (e.g A<sub>2</sub>) or non-A<sub>1</sub>B (e.g A<sub>2</sub>B). Blood samples for the initial and confirmatory subtype testing will be required to be taken on two separate occasions and be pre-transfusion specimens only.

The Committee had some concerns about the pre-transfusion aspect of the proposal because sometimes it is difficult to obtain pre-transfusion specimens. There was also some concern about disadvantaging O group candidates because of the small risk that patients are going to be transplanted with a mismatched organ, or an A<sub>2</sub> that is actually an A<sub>1</sub> versus the organs that could be transplanted into the group of patients that are already most disadvantaged. Does the risk of misdirecting an organ because of the inability to obtain a confirmatory test outweigh the risk of an inappropriate allocation because a confirmatory test was not performed? In other words, does general safety trump efficacy especially when the organs are not going to be wasted, is there a way we can modify this or make a recommended modification that can address some of the concerns about misdirecting organs that might otherwise go to someone who needs it more? Maybe it would be more cost effective to say it is best practice to do 2 confirmatory tests and let the transplant centers make their best judgment about the relative risks to their patients.

The POC recommends that the proposal be modified so that initial and confirmatory testing subtypes must be obtained unless transfusion precludes the confirmatory testing and in that instance, the decision about whether to accept those organs is the purview of the transplant center.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

14. Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport (Organ Procurement Organization (*OPO Committee*))

Summary of proposal: This proposed change makes the labeling requirements for vessel storage consistent with those for vessel transport. Recent Policy 5.0 changes eliminated the requirement that a label be placed directly on the vessel container for transport and require that the vessel label distributed by the OPTN contractor be attached to the outer barrier of the triple sterile barrier. Policy 5.10.2, currently requires the labeling of the vessel container when vessels are stored and requires the OPO to complete the labeling in the donor OR. As such, there is an inconsistency in vessel labeling requirements. This proposed policy modification will not affect the labeling requirements for vessel

transport, and will clarify that containers for vessel storage do not require the vessel container itself to be labeled. The vessels must be placed in a triple sterile barrier, one of which is the rigid container, and labeled with the OPTN distributed label.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

15. Proposal to Update and Clarify Language in the DCD Model Elements (*Organ Procurement Organization (OPO) and Organ Availability Committees*)

Summary of proposal: The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. As such, the name Model Elements has been changed to "Requirements." DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements:

- 1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and
- 2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.

Additionally, other policies that have the terms "Donation after Cardiac Death" will have to be modified for consistency.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

16. Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B (*Pediatric and Liver and Intestinal Organ Transplantation Committees*)

Summary of proposal: The Pediatric and Liver & Intestinal Organ Transplantation Committees propose that non-metastatic hepatoblastoma pediatric liver candidates should be listed immediately as Status 1B with elimination of the requirement to be listed at a MELD/PELD 30 for 30 days.

Hepatoblastoma is the most common primary liver malignancy in children. Optimal management of these patients usually includes a combination of chemotherapy and complete tumor resection. In some cases, a non-metastatic tumor may not be resectable by conventional means and may require a liver transplant to achieve a complete resection. In order to allow children with non-metastatic hepatoblastoma to be transplanted in a timely fashion, current UNOS policy allows these children to be assigned a MELD/PELD score of 30 at the time of listing. If the candidate is not transplanted within 30 days, the candidate may then be listed as Status 1B. The current Children's Oncology Group protocol for treatment of hepatoblastoma calls for no more than four of six rounds of chemotherapy prior to transplant, reserving two rounds for use following transplant. Since these patients must undergo chemotherapy while awaiting transplant, the optimal window for transplant is very small.

The Committee supported the proposal by a vote of 13 in favor, 0 opposed, and 1 abstention.

17. Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B (*Pediatric Transplantation Committee*)

Summary of proposal: The purpose of this proposal is to improve consistency in listing Status 1A and 1B pediatric liver candidates. The current requirement that a patient be located in the ICU uses location as a surrogate for severity of illness. Since the criteria for admission to an ICU varies from institution to institution across the country, the use of this surrogate creates inequality in Status 1A and 1B listings. In reviewing the other criteria for listing a Status 1A or 1B pediatric candidate, the Pediatric Transplantation Committee believes that these criteria are a stringent enough indicator of severity of disease that the ICU requirement may be eliminated without giving undue advantage to this subset of patients.

Currently, most of the cases where a patient is not in the ICU are exception cases that are generally approved by the Regional Review Boards. There was a question raised about whether this change will lead to Status 1A or 1B patients being outside the ICU. It was noted that the rest of the criteria for Status 1A and 1B candidates is stringent enough that the chances of that happening are small. It was also noted that the Pediatric Transplantation Committee will be able to assess this change by looking at the number of pediatric patients who are transplanted at Status 1B.

The Committee supported the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

**Attendance at the March 29, 2011 meeting of the OPTN/UNOS Policy Oversight Committee**

<u>Member</u>	<u>Position</u>	<u>Attended</u>
Stuart C. Sweet, MD, PhD	Chair	X
John Freidewald, MD	At-Large	X
David Axelrod, MD	At-large	X (phone)
Richard E. Pietroski, MS	At-large	X
Heung Bae Kim, MD	At-large	X
Laura Ellsworth	At-large	X
Silas Norman, MD	At-large	X
Mary Kelleher, MS, CIP	At-large	X
Kim Olthoff, MD	At-large	X
Steven Webber, MBChB	At-large	X
Amy Waterman, PhD	At-large	
Lee Ann Baxter-Lowe, PhD	At-Large	X
Timothy Stevens, RN, BSN	At-Large	X (phone)
Jean Davis	At-Large	X (phone)
Michael Green, MD, MPH	At-Large	X (phone)
Robert Walsh	Ex-Officio	X (phone)
Christopher McLaughlin	Ex-Officio	X (phone)
<b>UNOS Staff in Attendance</b>		
Erick Edwards, PhD	Assistant Director, Research	X
Robert Hunter	Policy Analyst/Liaison	X
Brian Shepard	Director of Policy	X
Mary D. Ellison, PhD	Assistant Executive Director	X
Vipra Ghimire	Liaison, Thoracic Organ Transplantation Committee	X
Jacqueline O'Keefe	Assistant Director, Membership	X
Lee Bolton	Liaison, Living Donor Committee	X
Kimberly H. Taylor	Liaison, Operations and Safety Committee	X
Ann Harper	Liaison, Liver and Intestinal Organ Transplantation Committee	X
Shandie Covington	Liaison, DTAC	
<b>SRTR Staff in Attendance</b>		
Bert Kasiske, MD, MS	SRTR	X
Jon Snyder, PhD, MS	SRTR	X