

OPTN/UNOS Patient Affairs Committee - INTERIM REPORT

Face-to-Face Meeting - March 28, 2011

- Departing Committee Members were given an opportunity for parting words. Departing PAC members were recognized with tokens of appreciation from Ray Gabel, PAC Chair. Departing members were also presented with UNOS Certificates by Laura Ellsworth, Vice-Chair

Cost estimates have been obtained for the *What Every Patient Needs to Know* rewrite. A possible sponsor has also been identified. Efforts are underway to secure a commitment for sponsorship. Donna Banks is leading the group in editing the current version of the rewrite.

The Committee's original goals for patient notification were to rewrite the Patient Notification Bylaws in plain language and to move the Patient Notification requirements from bylaw to policy. These goals have since been included in the UNOS Bylaw rewrite project. The remaining goal is to rename the UNOS Patient Information Letter. Renaming of the Patient Information Letter would need to go to Public Comment since it would involve a substantive change to the Bylaws.

The Committee previously considered requesting that Transplant programs be required to give the UNOS Patient Information Letter to living donor candidates'. Current policy only requires that living donor candidates be given the UNOS Patient Services Line Phone number prior to transplant.

Committee Members made the following comments during discussion about taking Living Donor Notification to Public Comment:

- The Patient Information Letter provides a tangible evidence of being officially in the transplant system
- Patient Notification for Living Donors is important for tracking the welfare and wellness of the Living Donor
- 'Why would we not give the Patient Information Letter to living donor candidates?'
- Providing the Patient Information Letter for living donor candidates is an extension of educating the recipient.
- Non-directed donors are often disconnected from the larger transplant process. Providing the Patient Information Letter provides an opportunity for non-directed donors to learn more about the system.

The Committee requested clarification on UNOS involvement with living donors. The Statistician was able to provide information regarding the UNOS initial involvement with living donors. The Statistician with the Living Donor Committee was also able to provide a general overview of the data that is collected on living donors and the follow up schedule for living donors.

The Committee agreed to move forward with a Public Comment proposal to provide Living Donor Candidates with the Patient Information Letter.

- The Committee heard an update from the Director of Patient Services on the Desensitization Project being considered in Congress. Desensitization is an issue for women and minority persons. This especially impacts persons who have multiple pregnancies, previous transplants or previous blood transfusions. These persons languish on the waiting list due to difficulties in finding an organ that will match. A process called plasma pheresis can in effect, wash the blood, enabling the candidate to safely accept organs from a greater pool of donors. While this process does not put more organs into the system, it does, potentially move candidates out of the system who would wait the longest. Medicare views pheresis very positively because of the significant cost savings related to transplant as compared with dialysis. NIH is currently funding a pheresis study at Cedars Sinai – Los Angeles. The Patient Services Director is working toward having NIH fund a multi-center study of the impact of plasma pheresis in moving highly sensitized candidates off of the waiting list.
- **Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Non-Contrast Computed Tomography (CT) Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability**

The Committee received the presentation. Committee members asked if OPO's have been resistant to this proposal due to the additional cost. There were also concerns that these costs would be transferred to transplant centers, and then indirectly to patients, without sufficient evidence that additional CT scans will significantly impact patient outcomes. Committee members further asked why this data is not being entered into UNET. In response, some parties use third party software. This proposal was developed based on anecdotal data. Through consistent monitoring of this policy, the Thoracic Committee hopes to obtain verifiable evidence, which would support programming into UNET. Further the Thoracic committee will monitor both policies 12.4 and 12.3. No specific time frame for monitoring was offered. The Committee voted in support of this proposal.

VOTE: Yes – 16, No – 0, Abstain - 0

- **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**

The Committee heard the presentation. The Committee felt strongly that the point should be made that status updates can be made more frequently if medically indicated. The concern was that some centers might interpret the 14 day requirement as the practice standard, and not a guideline. Lung Recipients on the Committee pointed out that the clinical status of Lung candidates can be very tenuous, changing very frequently. This makes the timing of status updates critically important. The Committee also questioned whether there is a scenario where lung candidates might lose priority for organs because of a decline in health status, which would be captured in the frequent reviews. The Committee voted to support this proposal with the caveat that the single lung recipient on the committee felt the 14 day time frame was arbitrary and could be problematic for the above stated reasons.

VOTE: Yes – 15, No – 1, Abstains – 0

- **Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time**

The Committee received the presentation. The Committee that this proposal would give candidates who are discharged home with a TAH and additional 30 days at Status 1A. Anecdotally, the Committee related that Status 1A patients are most often transplant. This same patient, in Status 1B at home would potentially languish on the waiting list, while technically meeting the same acuity as the TAH candidate who remains hospitalized. This creates an inequity in the system, which the Committee felt should be addressed. The Committee further felt that UNOS policy should never interfere with discharge home when clinically indicated and feasible. The Committee further affirmed the psychological and emotional benefits to being managed at home whenever possible. The Committee voted to support this proposal.

VOTE: Yes – 16, No – 1, Abstain – 0

- **Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates**

The Committee heard the presentation. The same donors are chosen for both liver-intestine candidates and small women. The Committee felt that this proposal gives preference to liver-intestine candidates, but may disadvantage both liver-alone candidates and smaller women at the local level. The Committee also felt that intestine-alone candidates might be disadvantaged, since through this proposal. The Committee further felt that there should be modeling of the impact on waitlist deaths for all candidate groups as a part of this proposal. The Committee voted not to support this proposal.

VOTE: Yes – 1, No – 9, Abstain – 6

- **Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation**

The Committee received the proposal. The Committee requested a strong informed consent process for candidates who are offered split livers. The consensus from the Committee is that split livers bring more livers into the donor pool. This allows the opportunity for more candidates to receive more transplants. The Committee would have liked to have seen estimates of the potential number of additional transplants that could be performed by this policy. The Committee voted to support this proposal.

VOTE: Yes – 14, No – 2, Abstain – 0

- **Proposal for Improved Imaging Criteria for HCC Exceptions**

The Committee received the proposal. The Committee asked for any evidence that current radiology results are not sufficient. The Committee also requested additional clarification on what constituted a transplant center radiologist. The Committee felt that this proposal could result in more appropriate allocation of livers, but may also have some negative cost ramifications with insurance companies due to increased radiologic testing. These costs would then, potentially be passed on to patients. The Committee

voted to support this proposal.

VOTE: Yes – 15, No – 1, Abstain – 0

- **Proposal to Require Confirmatory Subtype Testing of Non-A₁ and Non-A₁B Deceased and Living Donors**

The Committee Received the proposal. Many centers are already providing confirmatory results as part of their allocation process. It is believed that this contributes to the small numbers of reported rejection events annually due to donor ABO sub-typing incompatibility.

VOTE: Yes – 16, No – 0, Abstain – 0

- **Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B**

The Committee received the proposal. There was no discussion regarding this proposal.

VOTE: Yes – 1, N – 10, A – 3

- **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**

The Committee received the proposal. There was no discussion.

VOTE: Yes – 15, No – 0, A – 0

- **Living Donor Update**

The Committee received a chronological update on the development of the UNOS Living Donor Monitoring System. The presentation began in 1987, when UNOS first began collecting data on Living Donors. Current data maintained includes transplant data, donor status at discharge, 6 months, one year and two years post-transplant. The data currently collected includes donor-recipient relationship, serology's, donor social security number, donor complications, re-hospitalizations date and cause of death. The Committee raised questions about how time and cause of death are determined. UNOS cross references donor social security numbers with the Social Security Death Index and then personally contact the transplant center in an effort to obtain additional information. The Committee requested data on survival dates for living donors and center compliance with submission of Living Donor Data Forms.

- **Patient Information Sharing Task Force**

The Committee participated in a focused discussion on their experiences and expectations with information sharing with donor and recipients families, led by Committee Member and recipient and deceased donor mother, Kim McMahon. The following points were highlighted in the discussion:

- Some recipients find it difficult to write to their donor families
- The Committee feel that the Donor-Recipient system is hampered by staff turnover and lack of clear guidelines
- Staff need training on how to communicate with both donor and recipient families
- Centers need to have dedicated staff to address communication
- Recipients should be able to waive their HIPAA rights
- There is a need to develop educational materials on donor family communication

Each Committee member ranked a list of information which could be shared with donors and recipients by level of perceived importance. See the attached graph.

- **Ad Hoc International Relations Committee**

The Committee participated in a focused discussion regarding the management of UNOS Policy 6: Transplant of Non-resident Aliens. The Committee highlighted the following points during the discussion:

- The citizenship of deceased donors is fairly equal to the citizenship status of non-resident recipients. Contrary to popular opinion, non-residents are not disadvantaging US citizens by being transplanted here. Data was shown to support this statement.
- Illegal immigration is a significant political issue. This impacts the discussion significantly.
- Transplant of persons who arrive in the US under medical visa is a humanitarian act, and thus should be encouraged.
- Allowing persons from other countries to seek transplant in the US can be a double-edged sword: encouraging patients to seek health an ethical and safe system, but also discouraging persons of means from effecting the development of safe and ethical transplant systems within their own countries.
- Establishing clear definitions for non-resident and illegal aliens if imperative.
- All transplants should be monitored
- Equip center staff for recognizing candidates who have been coached to avoid detection as transplant tourists.
- Direct contribution to centers by candidates who come to the US for transplant should be monitored if not limited.

Transplant of non-resident aliens speaks to the innate human desire for survival. There are no straight-forward answers. There is a need for clarification of definitions and better monitoring. The availability of data and standards by which to monitor this data would

help in ascertaining the optimal scope for this policy, from a patient perspective.

- **Kidney Concept Proposal Document Discussion**

The Committee received a presentation on the Kidney Concept Proposal Document from Jim Gleason. The Kidney Concept Document was summarized as follows:

- Each kidney offered will be scored on a scale of 0 – 100. The lower the score the better the graft quality.
- Preferable grafts are those scored 0 -20. Grafts scored at greater than 20 are still acceptable. This replaces the current extended criteria donor concept.
- Twenty percent (20%) of the organs will go the candidates with the longest predicted longevity. The other 80% of organs will be allocated by age matching.

It was noted that there are 39 variances in Kidney Allocation. This was seen as an indication that the current Kidney Allocation does not work effectively. The PAC discussion is summarized below:

- This proposal opens the door for more donor education which targets seniors; or that population perceived to be most disadvantaged by the current proposal.
- There is concern that there may be a decline in living donation in response to the proposal.
- Older Adults will be disadvantaged. The outcomes from transplanting older organs into older candidates will not improve simply because they are age-matched.
- Fewer organs will be offered to Older Adults
- Potential to disadvantage persons on the cusp on adulthood, since their 15-year younger group will be PEDS. Pediatric candidates already have special consideration, which leaves this age group with only those who are 15 years older as their primary source.
- The major concern is that surgeons continue to have the final call in organ acceptance. Centers will also continue to have the same outcome requirements. Thus, there is still incentive for surgeons to turn down less than optimal organs. This proposal cannot address this problem.
- The formatting of the proposal makes it difficult to understand. A more user friendly format; incorporating a plain language abstract at the beginning, section headings, and call outs of significant points throughout the document will make proposals more accessible for the average reader.
- There would be great benefit to cultivating coverage with select audiences using respected media outlets such as AARP. It is important that any such efforts address the positives, while also providing a format to respond to negative feedback.

Overall, the Committee was very supportive of this proposal: Agreeing that this proposal addresses many common concerns regarding kidney allocation.

Ray Gabel adjourned the meeting at **3:30 PM Central Time**

Minutes submitted by: Freda M. Wilkins, MSW, M.Div, Committee Liaison