

OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

Summary

I. Action Items for Board Consideration

- The Board is asked to discontinue the Ohio Statewide liver alternative allocation system. (Item 1, Page 3)

II. Other Significant Items

- The Committee *did not* support the OPO Committee's proposal to 1) transfer responsibilities of labeling and packaging to the transplant center when the transplant center staff recover organs and 2) require a second unique identifier be included with the tissue-typing material container (Item 2, Page 5).
- The Committee supports the Kidney Transplantation Committee's proposal to include living donors and donor chains in the Kidney Paired Donation Pilot Program. (Item 3, Page 6).
- The Committee supports the Living Donor Committee's proposal to improve the ABO verification process for living donors. (Item 4, Page 7).
- The Committee *did not* support the Living Donor Committee's proposed guidance for the medical evaluation of living liver donors. (Item 5, Page 7).
- The Committee supports the Membership and Professional Standards Committee's proposal regarding OPTN notification requirements for OPOs, transplant hospitals, and histocompatibility labs when faced with an adverse action taken by other regulatory agencies. (Item 6, Page 8).
- The Committee supports the Membership and Professional Standards Committee's proposal to change the Bylaws to reconcile volume requirement discrepancies concerning full and conditional program approvals under training and experience pathways for kidney, liver, and pancreas transplant physicians. (Item 7, Page 8).
- The Committee supports the Membership and Professional Standards Committee's proposal to modify Policy 3.4.1. (Item 8, Page 8).
- The Committee supports the Ad Hoc Disease Transmission Advisory Committee's proposal to modify requirements for mandatory HTLV – 1 and 2 testing for all potential deceased donors. (Item 9, Page 9)

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November 16-17, 2009
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Edward R. Garrity, M.D., MBA, Chair

This report represents the deliberations of the Policy Oversight Committee during its September 9, 2009, conference call and its September 24th meeting in Chicago, Illinois.

1. Review of the Ohio Liver Alternative Allocation System (AAS). The Committee was provided with an overview of the various reviews of the AAS application submitted by the holders of the Ohio liver AAS. It was noted that this agreement was originally implemented in 1998. In 2008, the OPTN initiated a comprehensive review of existing variances, with the exception of kidney. This review led to the development of a standardized application form and information requirements in order to make sure that existing variances and applications for new variances meet the requirements of the OPTN Final Rule.

§121.8 [...] (g) Variances. The OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of §121.4. [...]

The various reviews of the Ohio Liver AAS are described below:

- In mid-2008, the Liver and Intestinal Organ Transplantation Committee formed a subcommittee to conduct the initial reviews. The subcommittee recommended the continuation of 6 of the AASs and did not support the continuation of 3 (Ohio, Florida, and Tennessee).
- Following discussions at the full Liver Committee meeting on July 29, 2008, the decision was made for the subcommittee to review the 3 AASs again prior to a full Committee conference call.
- The subcommittee again recommended the 3 AASs be discontinued. The Ohio AAS was recommended for discontinuation for the following reasons:
 - Restricts broader sharing
 - Has exceeded the “time-limited” or “experimental” period because it had been in place since 1995.
 - Could not be considered for use as a nationwide policy.
- The full Liver Committee discussed the AASs again in August 2008 and submitted the following resolution to the Board of Directors: “Resolved, that the Florida Statewide, Ohio Statewide, and Tennessee Statewide liver alternative allocation systems be discontinued, effective pending distribution of appropriate notice and programming in UNetsm.” (Committee vote: 13-0-0)
- The POC reviewed the proposal in October 2008 and agreed with the Liver Committee’s recommendation to discontinue the Ohio AAS. (Committee vote: 9-0-0)
 - The Liver Committee felt that the imposition of another layer between local and regional may disadvantage candidates within the region. The AAS has been in place since 1998, and there is no proposal to adopt this as national policy.

- Further, two organizations in the state that are subject to the AAS had indicated they no longer wished to continue participating in the agreement. The POC agreed with the Liver Committee's recommendation to eliminate this AAS.
- The Ohio Solid Organ Transplantation Consortium (OSOTC) sent a letter to UNOS President Dr. Robert Higgins in mid-Oct 2008 in response to the Liver Committee and POC recommendations.
 - OSOTC appeared to be agreeable to moving to a system that would make the state local. They expressed concern that in order to accomplish this change, a formal request to dissolve their current system must be submitted with the understanding the consortium would work under the national system until their new application can be submitted and reviewed through the process outlined in policy. UNOS staff has met with consortium representatives on several occasions to affirm that any new application will need to go through the process outlined in policy. They also considered asking to have the recommendations for dissolution set aside until the new system can be approved and programmed. Four individuals from Ohio were in attendance at the November 2008 Executive Committee meeting.
 - Dr. Charlie Miller (OHCC) made a presentation to the Executive Committee in November 2008.
 - The Board did not consider the recommendation to discontinue the Ohio AAS and referred the matter back to the Liver Committee for further consideration based on the availability of additional data.
 - Dr. Miller made a presentation to the Liver Committee in March 2009.
 - He noted that there were special circumstances in Region 10 and Ohio;
 - Ohio has 4 OPOs while Michigan and Indiana have only one OPO each;
 - Policy 3.6 allows for “local” allocation before regional placement, but this presumes that local allocation within a region is equitable;
 - Without this agreement, areas of Ohio will be transplanting lower MELD patients while higher MELD patients would not receive an available organ;
 - Application of a single rigid national allocation algorithm to variable definitions of local and regional can lead to inequitable allocation and distribution; and
 - AASs have been and remain the sole means to apply novel allocation algorithms to special geographic areas such as situations found in Region 10 that result in equitable allocation solutions.
 - The Liver Committee agreed to allow the AAS to continue in light of the new information and analysis plan, but asked the OSOTC to:
 - Provide more detailed goals and objectives;
 - Provide annual updates to the Liver Committee;
 - Consider redefining “local” for their AAS as multiple DSAs or investigate new models, noting that, without a change, the LSAM “experiment” is not an experiment.
 - The Committee may rescind the agreement on an annual basis. The AAS would also be dissolved if a new national allocation policy is approved in the interim. The Committee submits the following resolution to the Board for its consideration:
 - **RESOLVED, that Ohio Statewide liver alternative allocation system (AAS) shall be continued for up to three years. The AAS will be re-evaluated on an annual basis, and may be dissolved by the Board prior to the end of the three year period.
 - (Committee Vote: 11 in favor, 4 opposed, and 5 abstentions.)

Note: This resolution was removed from consideration by the Board until the AAS could be reviewed by the POC.

In accordance with its charge to review alternative system applications for compliance with the provisions of the Final Rule, the Committee reviewed the information provided and noted that there was no defined research design accompanying the application for this agreement. A member of the Committee commented that it appears that the Liver Committee attempted to infer or impose some sort of a research design on top of the submitted application during its discussions in March 2009 but that the application itself did not articulate one. The main argument being made for this agreement is that allocating livers locally and then to the rest of Ohio is more fair and constitutes broader sharing with regard to the patients in Ohio than it would be if livers are allocated using the national algorithm.

However, one of the primary issues remains that this type of agreement is not one that would be considered for use on a national basis, because it inserts a state boundary between local and regional sharing. There was a question raised about whether there has been any discussions regarding the geographical distribution of organs by OPOs. It was noted that HRSA would like to work with the Centers for Medicare and Medicaid Services (CMS) and the OPTN on this and evaluate better ways of distributing organs, including the issue of population versus geographical boundaries.

The Committee discussed the different scenarios that exist within Ohio but agreed that the final decision should be based on the information provided in the application and whether it meets the requirements defined in the Final Rule. The applicants expressed in one of their presentations that they would be willing to consider a single statewide list as “local” in lieu of each Ohio DSA serving as local. Such a proposal, however, would require the completion and approval of a new application. The Committee voted to dissolve the Ohio Statewide liver alternative allocation system by a vote of 9 in favor, 0 opposed, and 0 abstentions. Therefore, the Policy Oversight Committee submits the following recommendation for consideration to the Board of Directors:

****RESOLVED, that the Ohio Statewide liver alternative allocation system be discontinued, effective pending distribution of appropriate notice and programming in UNetsm.**

The Committee wanted to express that it understands the principles of equitable organ distribution and broader sharing. Further, the Committee would like to see Ohio submit a new application that moves toward broader sharing on a local level (e.g. a single statewide list), contains a detailed research design with measurable goals and objectives, and meets the requirements of the Final Rule.

Review of Proposals Circulated for Public Comment, July 2009 (Scores Provided in Table 1)

2. Proposal to transfer responsibilities of labeling and packaging to the transplant centers when they recover their own organs. The proposed modification transfers the responsibility of packaging and labeling of organs to the transplant center when the transplant center elects to recover its own organ(s) and is done in collaboration with the OPO. This proposal is in response to recent public comments, with the collective experience of the Committee, that suggest that the recovery teams (e.g. heart and lung teams) frequently leave the operating room without the benefit of labeling the organs and do not provide the OPO with the opportunity to do so. Current policy assigns this responsibility to the OPO, when the OPO may not have any control over this situation. Additionally, current policy requires that tissue-typing material containers be labeled with one unique identifier. This places OPO and hospital based laboratories in conflict with the Joint Commission (JC) requirements for accreditation when they accept tissue-typing material labeled with only one unique identifier. As such, the proposed change will require that tissue-typing material containers be labeled with two unique identifies in order to enhance patient safety.

The OPO Committee received feedback from OPOs and transplant centers regarding to the labeling and packaging process. Currently the OPOs are responsible for this, but there are occasions when the transplant teams will pack the organs in their coolers and leave the OR without properly labeling the organ(s). So the request was made to change the policy and transfer that responsibility to the transplant centers. There was a question raised about what happens if a procuring team takes an organ(s) out of that OPO and they need to be reallocated. It was noted that as long as the organ(s) are labeled properly, it shouldn't create a problem even if the organ(s) need to be reallocated. It was suggested that the OPO Committee consider policy language that creates a mechanism for disciplinary action if teams take an organ without proper labeling. There was also an opinion expressed that, especially in the case of thoracic organs, the OPOs should not be allowed to abdicate their responsibility of making sure organs are labeled properly. The procurement teams simply should not be allowed to leave the operating room until the proper labeling is complete. There was also a question raised about how often a labeling mistake is made and whether the OPO Committee reviewed any data.

The Committee recommends that the policy should not be changed, and the responsibility for the proper labeling and packaging of organ(s) should remain with the OPOs.

The second part of this proposal is to require the addition of a second unique identifier to the tissue-typing material containers. The question was raised about what should be used as the second identifier. It was noted that the OPO or transplant center would have the option of determining what the second identifier would be with the only stipulation being that it cannot be the donor ABO. The first identifier is the UNOS Donor ID number, and the OPO or transplant center would be required to have a policy stating what they would use as the second identifier. There was concern that this requirement needed to be articulated more clearly. It was noted that the Joint Commission requires two unique identifiers so hospitals would be out of compliance in terms of labeling various materials without two unique identifiers. It was suggested that the second unique identifier needs to be stated in the policy proposal so it doesn't create a great deal of variability across the country. The second unique identifier should be information that could be routinely obtained with the organ offer, and several suggestions were made including the donor birthday or last four numbers of the donor SSN.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 18.2. The proposal received an average score of greater than 2.0 in the following categories: Patient safety and transplant oversight, best use of donated organs, operational effectiveness, and statement of the problem.

The Committee *did not* support the two proposed changes to this policy as they are currently written.

Committee Vote: 1 in favor, 7 opposed, and 1 abstention.

3. Proposal to include non-directed living donors and donor chains in the Kidney Paired Donation Pilot Program. Currently, the Kidney Paired Donation (KPD) Pilot Program only allows living donors with incompatible potential recipients to participate. Non-directed (or altruistic) living donors (those who are not linked to an incompatible potential recipient) have no way to enter the program. Also, candidate / donor pairs can only be matched in groups of two or three, and all donor nephrectomies in the group must occur simultaneously. This proposal would allow non-directed living donors to participate in the KPD Pilot Program and add donor chains as an option in the system. A donor chain occurs when a non-directed living donor gives a kidney to a recipient whose living donor in turn gives a kidney to another recipient and continues the chain. This proposal would allow two types of donor chains: open and closed. Closed chains start with a non-directed living donor and end with a donation

to a recipient on the deceased donor waiting list. Open chains start with a non-directed living donor and end with a bridge donor who will start another segment in the open chain. In open chains, the bridge donor nephrectomy does not occur at the same time as the other living donor nephrectomies. Donor chains have the potential to increase the number of transplants in a KPD system.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 23.5. The proposal received average score of greater than 2.3 in every category except patient safety and oversight, geographical equity, and operational effectiveness.

The Committee unanimously supported this proposal by a vote of 9 in favor, 0 opposed, and 0 abstentions.

4. Proposal to improve the ABO verification process for living donors. The intent of this policy proposal is to improve the safety of living donation through an improved ABO verification and matching process.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 16. The proposal received average score of greater than 2.1 in the following categories: Statement of problem, degree of criticality, and patient safety and transplantation oversight.

The Committee unanimously supported this proposal by a vote of 9 in favor, 0 opposed, and 0 abstentions.

5. Proposed guidance for the medical evaluation of living liver donors. The Living Donor Committee has developed this resource to assist transplant professionals to medically evaluate potential living liver donors. This guidance can also inform and educate potential living liver donors about their own medical evaluations. **Please note that this resource is not policy and therefore does not carry the same monitoring implications.** The Living Donor Committee hopes to improve the care and follow-up of living donors by providing this information for voluntary adoption by transplant centers. The OPTN has previously approved a similar resource for the medical evaluation of living kidney donors.

Several Committee members felt the guidelines are too prescriptive because they contain a list of required tests. They felt the informational aspect of the guidelines were fine, but the bulleted list of what tests should be done are too detailed and prescriptive. This level of detail should be left up to the transplant centers or to the specialty societies that write recommendations/guidelines that could be used as a reference. It was also noted that even though the guidelines are not meant as “policy,” once approved some regulatory agency may see it as such. One member noted the OPTN needs to be very careful with these sort of guidance documents because of the sort of issues that came up with the kidney living donor resource document. There was some concern that this will by *de facto* establish a standard of care and potentially cause problems. It is one thing to have the professional societies proposing guidelines and quite another to have this coming from a Committee. There was also some concern about what evidence shows that donors are being harmed? There is the Adult to Adult Living Donor Transplantation Cohort Study (A2All) and a number of other studies that look at factors that affect donor harm and for the most part these provide accurate information about living liver donors. However, it was noted that UNOS has been charged with developing policies and resources for the safety and protection of living donors. It was noted that general guidelines are acceptable as long as they are not so prescriptive and detailed.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 11.2. The proposal received average score of greater than 2 in the following categories: statement of problem, evidence, and assessment.

The Committee did not support the proposed guidelines as currently written. Committee Vote: 1 in favor, 7 opposed, and 1 abstention.

6. OPTN notification requirements for OPOs, transplant hospitals, and histocompatibility labs when faced with an adverse action taken by other regulatory agencies. The MPSC suggested modifications to the bylaws that currently require OPTN notification by a member within 5 business days when a final adverse action is taken by a regulatory agency (or its designee). The proposed change would extend the notification period to 10 business days. The intent of this modification is to minimize the burden on OPO's, Transplant Hospitals, and Histocompatibility Labs by extending the length of time for reporting, removing the requirement to submit all materials relating to the issue, and only requiring notification when the adverse action is final.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 14.8. The proposal received average score of greater than 2.4 in the following categories: Statement of problem, evidence, and assessment.

The Committee supported this proposal by a vote of 8 in favor, 1 opposed, and 0 abstentions.

7. Proposal to change the Bylaws to reconcile volume requirement discrepancies concerning full and conditional program approvals under training and experience pathways for kidney, liver and pancreas primary transplant physicians. On July 1, 2006, the Board approved a recommendation from the MPSC to change primary transplant patient care volume requirements using the experience pathway to qualify as the primary physician at kidney, liver and pancreas programs. A complementary recommendation for appropriate adjustments reconciling these new values with expected volume numbers for conditional pathways was required, but did not occur. This proposal to change the bylaws will reconcile the volume discrepancies, which exist between the requirements for full and conditional approval of primary physicians at kidney, liver and pancreas transplant programs. The proposed language **does not change** the previously approved total volume requirements for full approval as the primary physician at kidney, liver and pancreas transplant programs when using either experience or training pathways. The intent is to remove the uncertainty for transplant programs, the MPSC and UNOS staff regarding the volume of patients required of proposed primary physicians for conditional approval and finally full approval.

The Committee used the scorecard to assess this policy, and the proposal received an overall score of 15.8. The proposal received average score of greater than 2.0 in the following categories: Operational effectiveness, statement of problem, degree of criticality, and patient safety and transplantation oversight.

The Committee unanimously supported this proposal by a vote of 9 in favor, 0 opposed, and 0 abstentions.

8. Proposal to add language to the Bylaws requiring transplant center and OPO members to follow state law regarding anatomical gifts. This proposal adds language to the bylaws that stipulates that members are obligated to follow their respective state laws regarding anatomical gifts. This bylaw will ultimately help to preserve public trust in the national organ transplant system by preventing conflicts of interest regarding declaration of death, organ procurement and transplantation being performed by the same person. The ultimate goal of this proposed change is to prohibit the same physician from declaring a patient's death and participating in the removal or transplant of organs from that decedent.

The Committee used the scorecard to assess this bylaw change, and the proposal received an overall score of 13.3. The proposal received average score of greater than 2 in the following categories: Statement of problem, operational effectiveness, and patient safety and transplantation oversight.

The Committee only voted on the proposed changes to the Policy 3.4.1. The Committee supported the proposal by a vote of 8 in favor, 1 opposed, and 0 abstentions.

Review of Proposal Circulated for Public Comment, August 2009 (Scores Provided in Table 1)

9. Proposal to modify requirements for mandatory HTLV- 1 and 2 testing for all potential deceased donors. Current policy requires anti-HTLV-1/2 antibody testing on all potential donors. Most OPOs currently use an enzyme immunoassay test system. This system will no longer be manufactured effective 12/31/2009. This leaves a high throughput testing platform as the only FDA-licensed commercially available alternative, which may not be amenable to the time constraints and logistics associated with prospective testing for organ donation at most OPOs. Based on the extremely low incidence (0.035-0.046% of blood donors) of HTLV-1/2 confirmed in donors, and the fact that there are no reported cases in the U.S. of transplant recipients infected with HTLV-1 that actually develop the disease, the Board of Directors voted to discontinue the requirement to perform prospective screening of deceased donors during its June 22-23, 2009 meeting. In response, the *Ad Hoc* Disease Transmission Advisory Committee recommends that retrospective HTLV-1/2 screening tests be required for all deceased donors, and that all screen positive tests be followed with confirmatory testing to differentiate between HTLV-1 and HTLV-2.

There was some concern that there is only a limited number of recipients who could possibly have HTLV transmitted to them on an annual basis. The main reason for this concern is the request to retrospectively test every single donor for the possibility of an infection to 4-6 patients when we have eliminated prospective testing. The chair of the DTAC noted that the reasons it is advocating for retrospective testing is: 1) that low number estimate is based on one OPO's data which may not be reflective of all OPOs across the country, and 2) the performance of the transplant community to date has suggested that even though that risk is very low, the transplant community has not utilized these organs very efficiently. As a result it was the opinion of the DTAC that this may represent enough of a concern that a very conservative approach be taken. That is why it is recommending retrospective testing instead of outright removal of all testing.

It was also noted that the retrospective testing can differentiate between HTLV 1 and HTLV 2, which is information not currently captured with prospective testing. Additional data are needed to make a more sound decision about HTLV and the risks it presents in transplantation. There is also the issue of public trust and the perception of discontinuing a test that was previously performed on every donor because of the cost.

The Committee used the scorecard to assess this policy change, and the proposal received an overall score of 14.2. The proposal received average score of greater than 2.2 in the following categories: Statement of problem and patient safety and transplantation oversight.

The Committee supported the proposal by a vote of 9 in favor, 1 opposed, and 0 abstentions.

Table 1	Labeling and Packaging of Organs	KPD non-directed living donors and donor chains	Living Donor ABO verification	Guidance for Med. Eval. of Living Liver Donors	OPTN Notification for Adverse Action
Patient Safety and Transplantation Oversight	2.6	1.6	2.9	1.3	1.2
Best Use of Donated Organs	2.0	3.0	1.9	0.4	1.0
Geographic Equity	0.0	1.7	0.0	0.0	0.4
Maximum Capacity	1.0	3.0	0.0	0.6	1.2
Operational Effectiveness	2.8	1.6	1.3	0.6	1.6
Statement of the problem	2.8	2.9	2.1	2.3	2.4
Evidence	1.4	2.3	1.7	2.1	2.4
Assessment	1.8	2.6	1.9	0.6	2.4
Patient Impact	1.8	2.4	1.9	2.0	0.6
Degree of Criticality	2.0	2.4	2.3	1.3	1.6
Total	18.2	23.5	16	11.2	14.8

Table 1 (continued)	OPTN/UNOS Bylaws – Volume Requirement Discrepancies	OPTN/UNOS Bylaws – Members to Follow State Laws	DTAC – HTLV 1-2 Retrospective Testing
Patient Safety and Transplantation Oversight	2.7	2.1	2.3
Best Use of Donated Organs	1.4	1.4	1.5
Geographic Equity	0.0	0.0	0
Maximum Capacity	0.6	0.9	0.8
Operational Effectiveness	2.1	2.3	1.4
Statement of the problem	2.3	2.1	2.2
Evidence	1.4	0.9	1.1
Assessment	1.9	1.3	1.4

Patient Impact	1.4	1.0	1.9
Degree of Criticality	2.0	1.3	1.6
Total	15.8	13.3	14.2
Each of the 10 categories may receive from -3 to 3 points, with zero being neutral.			

Other Discussion Items

10. Committee Orientation. UNOS staff provided a brief orientation, which outlined the Committee goals for 2009/2010 as well as initiatives being developed by other Committees. HRSA reminded the Committee that it was created by the current OPTN contract to provide a thorough analytic view to make sure policy proposals meet the goals and objectives of the OPTN Final Rule and follow guidance documents such as the policy development checklist. This Committee has a critical role of making sure things moving forward through the policy development process are based on appropriate evidence and have been thoroughly reviewed. It was noted that the Board is in a whole new world with regards to evaluating the cost of doing business and the impact policy changes have on the organization from a financial/cost point of view. HRSA also noted that it is supportive of expanding the role of the Committee and clarifying its role in other areas.

The Committee chair noted that the Committee developed a scorecard for reviewing policy proposals, and he expressed the importance of each committee member utilizing this important tool to assess the proposals. He also noted that it is not so much what the score ends up being but more of a measure of how each of the Committee members assess a new proposal and how it hits on aspects they feel are important. One Committee member noted that it is also important to put comments in the scorecard in order to provide important feedback to the sponsoring committees.

11. SRTR Orientation. The SRTR provided a brief orientation (**Exhibit A**) about the role it plays in providing analytic support for the OPTN committees. The data analyses provided help committees make decisions about policy changes and modifications as well as the evaluation of current policies. They also provide research support to various organizations as well as the scientific and transplant communities. Additionally, they develop and publish center-specific and OPO-specific reports and make regular reports on the status of solid organ transplantation.

12. Variance Proposal. UNOS staff was charged with revising the variance policies following a comprehensive review of existing variances in 2008. This review led to the development of a standardized application form and information requirements for describing an existing variance or submitting an application for a new variance. In order to continue the deliberate evaluation of each existing variance as well as any new variances, UNOS staff offered that the next step was to review and modify the variance policy language.

The Committee discussed the proposed modifications to the variance policies. These proposed changes to the policies would establish an appeals process for the review of variances, reorganize the policies, eliminate redundancy, and utilize plain language. During the discussions, the Committee was concerned about the definition of Local Unit and discussed the concept of local unit.

Additionally, HRSA expressed the following guidance:

- An approved variance is a policy;
- Perhaps the Committee should reconsider the definition of a local unit;

- The variance appeal process should be clear and should be attached to a time limit;
- The Committee should evaluate a new variance application's merit in terms of research design and its potential for inclusion in the national policy *before* the application's distribution for public comment;
- Certain variances may need to be in place for a time period that may not be perceived as temporary, and that the Committee should articulate this in policy;
- The variance application review must focus on the principles of research design: the appropriateness and feasibility of the research questions, hypotheses, and methodology proposed;
- In its review of the variance application as well as its review of an approved variance, the relevant committee must focus not just on data but on the research methodology employed in the variance; and
- The relevant committee must review each variance at a defined time period.

Upon hearing this discussion, as well the fact that this was the first time the Committee has discussed the proposal in detail, the Chair of the POC formed a working group to review the modifications and make certain that HRSA's concerns are addressed. The working group would make its recommendation to the full Committee.

13. Update on the Office of Management and Budget (OMB) Forms Review. UNOS staff provided an update on the OMB forms review process. **(Exhibit B)** OPTN data collection forms are reviewed and approved by the OMB and HRSA every three years, with the current forms expiring in November 2010. Several committees, the Ad Hoc Data Management Group (AHDMDG), an expert panel for kidney, the POC, Board of Directors, and HRSA are all involved in the forms review and revisions. The AHDMDG will review all proposed changes and make recommendations to the Committee. All the recommendations for changes will be combined into a single public comment proposal before being submitted to the Board of Directors for approval at its June 2010 meeting.
14. Policy Rewrite Project. UNOS staff provided an update on the policy rewrite project **(Exhibit C)**. The purpose of this project is to revise the policies using plain language, clarify the intent, modify the policy structure, and delete any outdated or redundant sections. This project is in response to the member survey results that suggest members had difficulty comprehending policy. Additionally, because of the incremental changes made to the policies over the years, there is a need for a systematic assessment of the policies. This project is scheduled to be completed in November 2010 following approval by the Board of Directors.
15. Concept for New Pancreas Allocation System. David Axelrod, M.D., provided the Committee with an overview of the pancreas allocation system being evaluated by the Pancreas Transplantation Committee. **(Exhibit D)**

The reasons for evaluating a new pancreas allocation system include:

- Current policy does not maximize the utilization of the pancreas in a population of uremic patients that benefits the most from kidney transplantation.
- The new kidney allocation system will not be allocating to simultaneous pancreas-kidney (SPK).
- A new opportunity exists to improve the national system for allocating pancreata, particularly in the context of SPK transplantation.
- New information on the pancreas donor risk index (DRI) provides insight into how donor characteristics impact SPK and PA (pancreas alone) outcomes.
- Recent data shows significant improvement of pancreas outcomes in PAK (pancreas after

kidney) recipients.

The goals of a new pancreas allocation system include:

- Increase utilization of the pancreas;
- Increase access for both SPK and PA (i.e, LD kid / PAK) candidates;
- Reduce waiting time for all pancreas candidates without adversely affecting adult and pediatric renal transplantation candidates;
- Reduce geographic inequities of access and waiting time; and
- Reduce the burden of disease of candidates of pancreas transplants.

There is a share 35 rule currently in place which basically means that kidneys from donors less than 35 years old are preferentially allocated to pediatric candidates (defined as being listed prior to the age of 18) after a limited number of exceptions. It was noted that the experience with the change in the thoracic organ allocation showed that an unintended consequence of the change was that now some of the organs from younger donors are going into older recipients. Suddenly there was a shift of younger organs into a much older age group to where there was a 300% increase in elderly recipients since the LAS went into effect. Dr. Axelrod noted that a benefit from the new proposed allocation system is that it could be a way of allocating kidneys from younger donors into, for example, a 25 year old diabetic instead of a much older recipient.

One of the things that might warrant discussion with the Pediatric Transplantation Committee is the issue of priority for pediatric candidates before SPKs. There is also the concern that type-1 diabetics could be differentially disadvantaged over any of the other groups that are waiting for kidneys but the LYFT (life years following transplant) and the potential consequences of staying on the waiting list are much higher for type-1 diabetics. However, type-1 diabetics only make up about 4% of the waitlist.

There was a question raised about how dependent this proposal is upon the new kidney allocation system is being developed. It could make the programming easier if some of the computer code is shared. Additionally, because of the number of variances that currently exist, eliminating some of the pancreas variances would actually make it easier to allocate pancreata.

**Attendance at the September 9, 2009 Conference Call of the
OPTN/UNOS Policy Oversight Committee**

Member	Position	Attended
Edward Garrity Jr., MD, MBA	Chair	X
John Freidewald, MD	At-Large	X
David Axelrod, MD	At-large	X
Lori Brigham, MBA	At-large	X
David Campbell, MD	At-large	X
Laura Ellsworth, MBA	At-large	X
Silas Norman, MD	At-large	X
Mary Kelleher, MS, CIP	At-large	X
Kim Olthoff, MD	At-large	X
Mark Barr, MD	At-large	
David Meltzer, MD, PhD	At-large	
Robert Walsh	Ex-Officio	X
Robert Merion, MD	SRTR Representative	X
UNOS Staff in Attendance		
Erick Edwards, PhD	Assistant Director, Research	X
Robert Hunter	Policy Analyst/Liaison	X
David Kappus	Assistant Director, Membership	X
Karl J. McCleary, PhD, MPH	Director, Policy, Membership, and Regional Administration	X
Sally Aungier	Liaison, MPSC	X
Lee Bolton	Liaison, Living Donor Committee	X
Jacqueline O'Keefe	Performance Analyst Manager	X
Elizabeth Sleeman, MHA	Liaison, Pancreas Committee	X
SRTR Staff in Attendance		
Robert Merion, MD	SRTR Representative	X

**Attendance at the September 24, 2009 Meeting of the
OPTN/UNOS Policy Oversight Committee
Chicago, IL**

Member	Position	Attended
Edward Garrity Jr., MD, MBA	Chair	X
John Freidewald, MD	At-Large	
David Axelrod, MD, MBA	At-large	X
Lori Brigham, MBA	At-large	X
David Campbell, MD	At-large	X
Laura Ellsworth, MBA	At-large	By Telephone
Silas Norman, MD	At-large	X
Mary Kelleher, MS, CIP	At-large	X
Kim Olthoff, M.D.	At-large	X
David Meltzer, MD, PhD	At-large	X
Mark Barr, MD	At-large	X
Christopher McLaughlin	Ex-Officio	X
Robert Walsh	Ex-Officio	X
UNOS Staff in Attendance		
Erick Edwards, PhD	Assistant Director, Research	X
Robert Hunter	Policy Analyst/Liaison	X
Mary D. Ellison, PhD, MSHA	Assistant Executive Director for Federal Affairs	X
Karl J. McCleary, PhD, MPH	Director, Policy, Membership, and Regional Administration	X
Vipra Ghimire	Policy Analyst	By Telephone
Chad Waller	Policy Analyst	By Telephone
Lee Goodman	UNOS IT, Engineer	X
Elizabeth Sleeman, MHA	Liaison, Pancreas Committee	By Telephone
SRTR Staff in Attendance		
Randall Sung, MD	SRTR Representative	X
Erick Roys	SRTR Representative	X