

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Annual Set of Committee Initiatives 2012-2013

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Background

The Organ Procurement and Transplantation Network (OPTN) Board and Committee system represents one of the network's most powerful mechanisms for improving transplantation in the U.S. It has established virtually all of the OPTN policies and bylaws according to which the network operates today. On it depend many of the future improvements necessary for the field to thrive. It is unique in its history of drawing upon impressive intellect, expertise, energy, and volunteer spirit of hundreds of transplant professionals, patients, donor families, and members of the public. Through them, the OPTN Committees and Board have built and continually improved the national transplant system.

UNOS operates the OPTN under contract with the Department of Health and Human Services. This contract includes a number of tasks and deliverables that directly address the OPTN Board and Committee system and their crucial role in the development and oversight of OPTN policies and bylaws. These policies and bylaws, together with the National Organ Transplant Act (NOTA) and the OPTN Final Rule, provide the framework for many activities and operations of the OPTN. Therefore, in the current OPTN contract, considerable emphasis is placed on Committee and Board productivity and efficiency. There is also emphasis on the Committees' work being focused, goal-oriented, and consistent with both long- and short-term aims adopted by the organization.

Resources available for OPTN support and operations are limited – both for policy development and implementation. It has also become clear that virtually every feature added to the OPTN data system or internal operations is additive, requiring resources not only for initial implementation but also for maintenance in perpetuity, most often in the form of additional personnel. Additionally, the nature of the work is such that few changes impact only one aspect of operations. For this reason, together with contract requirements, it has become necessary to streamline and clearly articulate going into each annual Board and Committee cycle (begins each year following the June Board meeting) the priority initiatives for the coming year. Most complex initiatives require multiple years to come to fruition. Neither evidence-based nor consensus-based policy development is done well under deadlines. For this reason, the fact that goals are articulated annually does not imply deadlines or timing.

The history of annual Committee goal development began in October 2005, when the OPTN/UNOS President convened five working groups that had been working through the fall. These were made up of members of the Board of Directors; Committee chairs, representatives of a number of societies including AST, ASTS, AOPO, ASHI, ISHLT, and NKF; and various invited guests from the community to prepare for and participate in an October strategic planning meeting in Boston. Activity and discussion were organized around these objectives, which became known as the OPTN Strategic Plan:

1. Increasing the number of organs transplanted
2. Supporting live donor transplantation
3. Consideration of net benefit as applied to organ transplantation
4. Differences in the opportunity for transplant within the U.S., and
5. The collection of clinically relevant and validated data.

During ensuing years, these objectives have been only somewhat modified as leadership has changed and as increased emphasis on safety and oversight became necessary. Other objectives have been broadened but have remained true to their original themes. The key challenge areas pursued by this Strategic Plan, updated by leadership during 2008, are as follows:

1. The Donor Shortage
2. Living Donor Safety
3. Improving Allocation Principles
4. Reduce Variation in Access to Transplantation
5. Oversight of Transplantation, Role of OPTN
6. OPTN Operational and System Effectiveness

At the November 2010 meeting in St. Louis, the OPTN/UNOS Board of Directors endorsed a new planning process that will help the board focus on OPTN and UNOS projects that have the potential for the greatest impact on transplant patients. The goal of this new process is to evaluate and prioritize new projects at an early stage in their development in order to make the best use of finite resources, including the time and effort of the committees. Committees submitted a list of projects for the upcoming year and each of the projects were categorized according to the 5 key goals established by the Board:

1. Increase the number of transplants.
2. Increase access to transplants.
3. Improve post-transplant survival.
4. Promote transplant patient safety.
5. Promote living donor safety.

Committees have been developing annual work plans for several years but this new process includes one additional step—prioritization. The first work on the prioritization was made by the OPTN/UNOS Policy Oversight Committee (POC) during its March 29, 2011 meeting. The Executive Committee was asked to consider the POC's recommendations during their review in the June 2011 Board of Directors Meeting and suggested a share of project development time for each of the five key goals. The Board of Directors has the ultimate authority for approving the overall OPTN work plan.

At its meeting on June 25-26, 2012, the Board approved the OPTN Strategic Plan with the following six key goals:

1. Increase the number of transplants;
2. Increase access to transplants;
3. Improve survival for patients with end stage organ failure;
4. Promote transplant patient safety;
5. Promote living donor safety; and
6. Promote the efficient management of the OPTN.

OPTN Vision Statement

The OPTN promotes long, healthy, and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation; and doing so by balancing competing goals in ways that are transparent, inclusive, and enhance public trust in the national organ donation system.

General Committee Guidance

Generally speaking, Committees report to and act through the Board. Activities of a Committee and correspondence from a Committee or its leadership must be coordinated through the UNOS staff Committee liaison. The liaison will work with the chair and the Committee to get any necessary approvals for Committee correspondence and for activities not budgeted, planned, or routine for the work of the Committee. Each Committee plays a role in the larger OPTN policy development process. As such, the Committee is an agent of the Board of Directors, which oversees all of its actions and activities. In certain circumstances, the President of the Board, the Executive Director and/or the Executive Committee may be able to approve documents or activities of the Committee between Board meetings.

Committee Initiatives for 2012-2013

The Annual Committee goals that follow for 2012-2013 are intended to further the OPTN's work in at least one of the 6 key challenge or Strategic Focus areas and to guide the Committees in the prioritization of the work they undertake during the coming year.

Committee Charge and Initiatives for 2012-2013

(Ad Hoc) Disease Transmission Advisory Committee (DTAC)

The DTAC considers issues related to the transmission of disease through organ transplantation. The Committee examines individual potential disease transmission cases reported to the OPTN in an effort to confirm transmissions where possible. It reviews aggregate data on all reported cases to assess the risk of donor disease transmission in organ transplantation in the U.S. with the goal of providing (1) education and guidance to the transplant community toward preventing future disease transmission and (2) input in developing policy to improve the safety of organ donation through the reduction of donor derived transmission events. It may identify disease-transmission related patient safety issues to be addressed, as appropriate, by the OPTN.

Project Title:	Project Description:
What to do when serology results are updated: Potential Modifications to Policies 2.2.5, 2.2.6, and 3.2.4	Joint - DTAC, OSC, and OPO Project; Concerns were raised regarding the need for policy to require a match be re-run when new serology results are received prior to transplant. New policy language may be required to help prevent possible recurrence of this scenario and promote patient safety in allocation of organs where new testing results could affect recipient outcomes.
Modification to OPO Post-Transplant Reporting of New Donor Info (Policy 2.2.5)	Joint - DTAC and OPO Project; Requiring voice-to-voice contact when sharing new donor information received post-transplant (e.g. final culture or autopsy results) that is relevant to acute patient care enhances patient safety by removing the chance for this information to be lost or overlooked via fax, email, etc.. Both the DTAC and the OPO Committee have been asked to consider voice-to-voice communication as a more dependable means to get critical post-transplant donor information to the “right” person at a transplant center. The Committees will discuss the practicality and feasibility of using the patient safety contact list to make voice-to-voice contact when sharing this information. This would eliminate lost or missed faxed reports or emails that are not opened in a timely fashion. The Committees will consider possible modifications to Policy 2.2.5 to add this requirement.

<p>Review of Minimum Screening Requirements for Deceased Donor Evaluation</p>	<p>The current screening test requirement stemmed from changing test kit availability and a widely publicized transmission event in late 2008. Policy language was originally recommended by the Executive Committee. The DTAC plans to:</p> <ul style="list-style-type: none"> • review the availability of current FDA-approved donor screening tests to determine whether policy language requiring the use of screening tests when commercially available is appropriate • consider the term “commercially available” and provide either a clear definition or new terminology in its place; and • consider whether allowing only screening kits for HIV without exception is appropriate based upon changes to test kit availability and new technology.
<p>Modifications to Require Toxoplasma Screening During Evaluation of Deceased Donors</p>	<p>Enhanced donor screening is suggested by the Committee as a way to potentially decrease the number of unexpected Toxoplasma transmissions since this screening is handled on an ad hoc basis by sending blood with the heart. Positive results may not always be communicated back to the OPO or to other organ recipients. Toxoplasma screening is not currently required by policy as part of the deceased donor evaluation. The Committee reviewed a number of proven transmissions where transmission may have been prevented if prophylaxis was provided based upon known donor results. For this reason, the Committee would like to pursue this proposed requirement again</p>
<p>Revise the Deceased Donor Import Policy to Comply with NOTA and the OPTN Final Rule</p>	<p>The proposed policy modification will accurately state what happens when the OPTN Contractor offers an organ recovered by a foreign agency.</p>
<p>OPO Screening Practices Survey</p>	<p>The DTAC seeks to conduct a follow-up to its 2008 survey of all OPOs regarding donor screening practices to determine how practices have changed based upon changing test kit availability and the new US PHS exclusionary guidelines that were expected for release in Spring 2010. (This project will be on hold until these new high risk guidelines are released in an effort to determine if they change testing practices).</p>

Improvements to Potential Donor-Derived Disease Transmission Reporting Page in Patient Safety Portal

Problem the committee seeks to address: There are a number of inefficiencies related to the current portal for patient safety events to the OPTN. There are concurrent efforts planned to address to Patient Safety, Living Donor Adverse Event and Potential Donor-Derived Disease Transmission reporting pages to make reporting more efficient for both the OPTN member and UNOS staff that processes reported information. The DTAC effort will focus specifically on the disease transmission reporting page.

Ethics Committee

The Ethics Committee is established for the general purpose of considering ethical issues related to organ procurement, distribution, allocation, and transplantation. These issues include social impact, the relationship of cost to benefit, impact on patients and their families as well as society at large, legal issues and related public policy, and access to transplantation.

The Ethics Committee offers policymaking committees the framework to develop policies and activities that are consistent with accepted ethical principles. The committee also produces informational and educational articles to stimulate discussion among the transplant community and the public about emerging ethical issues. The committee considers ethical issues with broad applicability and does not review specific events.

<p>Review multi-organ allocation policies</p>	<p>Multi-organ allocation policies are often confusing to members and contain some ambiguities. What this does is create problems during organ allocation for both OPOs and transplant centers and makes it difficult for compliance personnel and committees/MPSC to identify and adjudicate potential violations. Review the existing policies to see what works and what doesn't and recommend changes. Provide some general recommendations about overarching principles to address important issues such as eligibility, equity, and utility. Potential minimum listing criteria for the various types of multi-organ transplants. This approach would require the most time and effort and could potentially require a significant amount of computer programming.</p>
<p>Uncontrolled DCD (u-DCD) Model Elements</p>	<p>An OPO subcommittee has developed a survey to determine current practice and to identify whether or not the term "uncontrolled" appropriately describes the process. Setting protocols for uncontrolled DCD recovery could provide a better understanding of the practice and increase the number of organs recovered.</p>
<p>Revise National Kidney Allocation System</p>	<p>Problem the committee seeks to address: High discard rates of kidneys (especially those from expanded criteria donors [ECD]) that could benefit candidates on the waiting list, variability in access to transplantation by blood group and geographic location, and many kidneys with long potential longevity being allocated to candidates with significantly shorter potential longevity and vice versa. This results in unrealized graft years and unnecessarily high retransplant rates.</p>
<p>Modify Pediatric Heart Allocation Policy</p>	<p>Modify Pediatric Heart Allocation Policy</p>

Histocompatibility Committee

The Histocompatibility Committee considers issues relating to donor and recipient histocompatibility, organ allocation, histocompatibility testing, and histocompatibility laboratory and personnel qualifications. The goal of the Committee’s work is to promote patient safety, good transplant outcomes, and best use of organs.

Project Title:	Project Description:
<p>Proposal to update the “HLA Antigen Values and Split Equivalence table” and the “HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalence” table as found in Policy 3 Appendix A as required by policy</p>	<p>The purpose of this proposal is to update the tables in Appendix 3A to reflect changes in HLA typing practice and to improve the utility of the unacceptable antigens. Appendix 3A includes 2 tables: • A table listing HLA antigen designations that should be considered equivalent for purposes of matching kidney candidates and donors for the HLA-A,-B, and – DR antigens (HLA Antigen Values and Split Equivalences) • A table to determine which donor HLA antigens are unacceptable based on the unacceptable HLA-antigens listed for a sensitized candidate (HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences). Accurate equivalence tables are essential to accurately allocate organs that include HLA as a factor in its allocation algorithm.</p>
<p>Addition of Elements to Waitlist and DonorNet -DP beta (DPB) and DQ alpha (DQA)</p>	<p>By using the most current HLA antigens that can be readily supplied by a HLA laboratory we will more accurately predict the probability of an incompatible match with the current donor pool. Allowing centers to list DPB and DQA not only as antigens but as unacceptables will make the allocation process more accurate and more effective and thereby more efficient with less likelihood that a kidney would be shipped to a highly sensitized candidate and not be used in that candidate because of an unexpected positive crossmatch.</p>
<p>Oversee implementation of a sliding scale for sensitization points awarded for CPRA in the new kidney/pancreas allocation system & Develop tools for dealing with candidates who have undergone desensitization</p>	<p>The committee plans to work with the Kidney and Pancreas committees in the upcoming year to make sure they are addressed in the new allocation systems.</p>

<p>Update Calculated Panel Reactive Antibody (CPRA)</p>	<p>In October 2009, the OPTN implemented Policy 3.5.11.3 which effectively replaced a Panel Reactive Antibody (PRA) value with a Calculated Panel Reactive Antibody (CPRA) value for Kidney, Kidney/Pancreas and Pancreas and significantly changed kidney and pancreas allocation. (The CPRA is simply the frequency of incompatible donors an individual may encounter while waiting for an organ offer.) Based on post-implementation data analyzed by the Histocompatibility Committee, the policy has been very effective and has yielded many benefits. However, the CPRA is based on older technology; to maximize its effectiveness some major updates should be made.</p>
<p>Monitor CPRA</p>	<p>The Committee will continue monitoring the implementation of CPRA, including blinded center and lab related differences in CPRA and transplantation of sensitized patients, as well as offers declined because of a positive crossmatch. The Committee feels that the transplant community as a whole could use some guidance as to how to use CPRA for the best of the patient, especially because its use is still relatively new.</p>
<p>Rewrite of the Histo standards within OPTN/UNOS Policy and Bylaws</p>	<p>Currently, the UNOS bylaws, the OPTN Bylaws and the OPTN Policies that govern HLA laboratories are a scattered. There is not a central location, requirements are scattered throughout all of the above. A large portion of the regulations should not even be in the bylaws or in policy, and should be removed. A new cross walk that would reflect the current state of affairs cannot be initiated until our standards are in order.</p>

(Ad Hoc) International Relations Committee

The Ad Hoc International Relations Committee considers issues related to organs and patients that enter or leave the United States (U.S.) for transplant. It reviews emerging issues related to U.S. candidates who seek transplants in other countries, and it considers the medical, scientific, and ethical aspects of transplanting non-resident aliens. The committee considers the broad implications of such issues and may review specific individual issues or situations.

<i>Project Title:</i>	<i>Project Description:</i>
<p>Study and Consider Policy Modification Regarding the Import and Export of Living Donor Organs</p>	<p>Joint - AHIRC and Living Donor Committee Project; The Committee has received inquiries regarding the import and export of living donor organs. Current policy permits the export of living donor organs. Current policy prohibits the import of living donor organs from another country. Policy 6.4 allows for the export of organs, however, this policy has been typically understood to apply to deceased donor organs. So, current policy could be clearer on whether such organs could be exported.</p>
<p>Define “Exhausting the Match Run”</p>	<p>Joint - AHIRC and OPO Project; With a concrete definition of exhausting the match run, it is possible that organs that might have been discarded due to poor cold ischemic times might be more likely to be used. Defining what it means for an OPO to exhaust the match run will eliminate ambiguities about when OPOs can offer organs to foreign hospital. Exhausting the match run is a concept that is not well defined in current policy.</p>

Kidney Transplantation Committee

The Kidney Transplantation Committee is charged with considering medical, scientific, and ethical aspects related to kidney organ procurement, distribution, and allocation. The Committee considers both the broad implications and the specific member situations relating to kidney issues and policies. The goal of the Committee's work is to develop evidence-based policies aimed at reducing the burden of renal disease in transplant patients (candidates and recipients), increasing kidney utilization, improving access to kidney transplantation as appropriate, and improving the health outcomes of kidney transplant recipients, fostering access to transplantation and good outcomes for patients (including waiting candidates and living donors) involved in kidney transplantation.

Project Title:	Project Description:
Revise National Kidney Allocation System	Problem the committee seeks to address: High discard rates of kidneys (especially those from expanded criteria donors [ECD]) that could benefit candidates on the waiting list, variability in access to transplantation by blood group and geographic location, and many kidneys with long potential longevity being allocated to candidates with significantly shorter potential longevity and vice versa. This results in unrealized graft years and unnecessarily high retransplant rates.

Kidney Paired Donation Workgroup

The kidney paired donation workgroup will facilitate a system that will allow multiple transplants to occur where the transplant opportunities otherwise would be lost by building on the successful efforts of regional KPD programs to establish a national KPD matching pool. The KPD workgroup will implement a pilot program and develop interim policies as a step toward a permanent program.

<i>Project Title:</i>	<i>Project Description:</i>
Revising KPD Priority Points	Altering the priority points for distance for KPD should help to increase participation. Increased participation means more pairs in the pair pool, particularly easy to match pairs, which will increase the number of matches and transplants found through the OPTN KPD Program. The Work Group is exploring whether increasing the points for matches at the same center would make centers more comfortable with entering their easy to match pairs.
Converting KPD Operational Guidelines into Interim Policy	Currently, the only action the MPSC can take against a program for violating the KPD operational guidelines is to remove them from participating in the program. Converting the operational guidelines into policy would allow the MPSC to consider the full range of adverse actions for a program that violated the KPD policy. The KPD Work Group and the Kidney Committee will take the existing Operational Guidelines and make them policy instead, including public comment. These interim policies will only apply to exchanges facilitated through the OPTN KPD Pilot Program. Future permanent policy, after the Pilot, may apply to other KPD programs.
Allowing Open Chains in the OPTN KPD Pilot Program	Open chains have the potential to increase the number of transplants in a KPD system. However, there are some concerns in the transplant community about the logistical and ethical considerations in incorporating open chains. The committee seeks to work through these concerns, if possible.
KPD Automated Solution	Currently, the OPTN KPD Pilot Program is being operated using a manual solution. The committee seeks to automate the program.

Liver and Intestinal Transplantation Committee

The Liver and Intestine Transplantation Committee considers medical, scientific, and ethical aspects related to liver and intestine organ procurement, distribution, and allocation. The committee considers both the broad implications and the specific members' situations of these liver or intestinal issues or policies. The goal of the Committee's work is to develop evidence-based policies aimed at reducing the burden of liver disease in transplant patients (candidates and recipients), increasing liver utilization, improving access to liver transplantation, and improving the health outcomes of liver transplant recipients.

Project Title:	Project Description:
Update Policy 3.6.5.1 (Execution of the Liver Match System)	The Committee was asked to clarify the intent of this policy, i.e., when it is permissible to re-execute the match. In reviewing the policy the subcommittee felt that it was out of date (for example, the term "Match system printout" is outdated) and confusing. The Committee plans to revise policy for clarity, bring it up to date with current practices, and promote more effective placement of organs.
Revisiting the PELD score	The PELD score has not been updated since 2001. Currently, one-half of pediatric patients are listed with a PELD exception, indicating the need to revisit the score's applicability. The current PELD score does not accurately predict pre-transplant mortality.
RRB: Standardizing the Heart, Liver, and Lung Review Board Processes	Joint - Liver and Thoracic Project; Existing policy and RRB guidelines create over two dozen different permutations for the review of status and score exceptions. This creates unnecessary complexity, cost, and uncertainty in the system. The review board functions should be streamlined and standardized across organ types where appropriate. A goal of this project is to create efficiency in manual and automated efforts required to manage requests for exceptions submitted to the regional and national review boards.
Requirements for Intestinal Transplant Programs	There are no criteria for intestine transplant surgeons and physicians, despite the fact that this practice has been growing.

<p>Facilitated placement / reduced discards</p>	<p>Currently, livers are being placed in an expedited manner but without any national policy for guidance, and thus the process lacks transparency. Further, livers are being discarded that could be used do to the lack of a formal process for expedited/facilitated placement. The Committee is interested in identifying factors associated with discard in hopes that better education may reduce discard.</p>
<p>Liver Distribution Redesign Modeling</p>	<p>Geographic disparities remain in access to transplant, waiting list deaths and transplant rates.</p>
<p>Allocation of livers for hepatocyte transplants</p>	<p>Hepatocytes can be used as a 'bridge' to transplant for critically ill patients, and/or may be curative for some metabolic disorders. However, the current allocation sequence places these candidates at the very bottom of the national list. The Committee has been asked to re-evaluate this policy.</p>
<p>Additional Priority for DCD Recipients That Require Retransplant</p>	<p>Recipients of DCD livers have a higher probability of graft failure and/or ischemic biliary strictures than non-DCD donors, potentially requiring immediate or later retransplant. This may create a disincentive to use these donors. A policy similar to that for patients with HAT/PNF would provide a safety net in these cases (the HAT/PNF policy was in part put in place to provide a safety net when centers opt to use less-than-ideal donors).</p>
<p>Enhancements to the MELD score / Liver Allocation (HCC Allocation Score/MELD Refit)</p>	<p>The Committee continues to investigate ways to reduce waiting list death while not harming post-transplant survival by tweaking (or potentially replacing) the MELD score.</p>
<p>Ongoing review of Status 1A/B Cases not meeting criteria</p>	<p>Centers may list patients in Status 1 who do not meet the criteria subject to automatic review. As Status 1 candidates receive regional offers it is important to verify that these patients are truly in need of Status 1 listing.</p>
<p>Ongoing review of MELD/PELD Exceptions (HCC HOLD)</p>	<p>The number of MELD exceptions has been steadily increasing. This is causing an increase in the MELD score required for transplant in many regions, disadvantaging patients listed with a calculated score.</p>

Living Donor Committee

The Living Donor Committee considers issues relating to the donation and transplantation of organs from living donors to recipients. The Committee also provides guidance to staff and other Committees in development of public communications and educational materials related to living donor transplantation. The goal of the Committee’s work is to improve the processes of living donation and living-donor transplantation and to foster the safety of living organ donors.

Project Title:	Project Description:
Require all recipients of Living Donor Organs to be Registered in UNET prior to Transplantation	Require UNET registration for all recipients of Living Donor Organs prior to transplantation.
Improving the Reporting of Living Donor Status	Improving the reporting of living donor status.
Develop Policy to Establish Minimum Standards for Living Liver Donor Follow-Up	Develop Policy to Establish Minimum Standards for Living Liver Donor Follow-Up
Develop Policy for the Medical Evaluation of Living Liver Donors	Develop policy for the medical evaluation of living liver donors
Develop Informed Consent Policy for Living Liver Donors	Develop Informed Consent Policy for Living Liver Donors
Update the Living Donation Brochure	The UNOS Professional Services department previously coordinated the development of a resource titled: Living Donation Information you need to know. The resource is available in English and Spanish, and is distributed free of charge. Some of the content is this resource is now outdated.
Consider Which Living Donor Program Metrics should be Available to the General Public	In order to provide true informed consent, potential living donor and members of the general public should be able to compare and contrast transplant centers’ outcomes, complication rates, and donor follow-up rates. Recommend which living donor program metrics should be reported publicly, and recommend how such reporting should be accomplished.

<p>New Requirements for the Transport of Living Donor Organ (rewrite policy 12.7) (Kidney)</p>	<p>Project has been on hold during the past year based on the assumption that living donor organ transport requirements would be required/developed through the KPD pilot. Now that such transport requirements won't be addressed through the KPD pilot the LD Committee will resume this work.</p>
<p>Develop Policies for the Medical Evaluation of Living Donors- Kidney</p>	<p>The OPTN will form a working group, including but not necessarily limited to AST, ASTS, and NATCO representatives as well as OPTN Living Donor Committee members (including living donors) to develop draft elements to be included in the living donor transplantation protocols that OPTN policies require to be adopted and followed by all programs performing living donor transplants.</p>
<p>Develop Living Donation Consent Policies- Kidney</p>	<p>The OPTN will form a working group, including but not necessarily limited to AST, ASTS, and NATCO representatives as well as OPTN Living Donor Committee members (including living donors) to develop draft elements to be included in the living donor transplantation protocols that OPTN policies require to be adopted and followed by all programs performing living donor transplants. The working group will consider using CMS Conditions of Participation as the starting point for development of the elements to ensure consistency and reduce burden on transplant programs</p>
<p>Guidance for Living Donor Advocates- Kidney</p>	<p>Results of the Living Donor Program Survey and preliminary results of the Living Donor Program Audits have demonstrated that there is wide variability in how centers provide Independent Donor Advocates (IDAs), and ongoing confusion about requirements for donor advocates. Preliminary results from our living donor program survey reveal that only 79% of living kidney programs and 87% of living liver donor programs reported having an independent donor advocate or donor advocate team (in violation of the bylaws). Living donor program auditors have reported to the LD Committee that transplant centers are requesting guidance on the role and requirements for IDAs.</p>

Membership and Professional Standards Committee (MPSC)

The Membership and Professional Standards Committee (MPSC) considers requirements that clinical transplant centers, organ procurement organizations, and histocompatibility laboratories, and non-institutional members must meet to be members of the OPTN and UNOS, as established in the OPTN and UNOS bylaws. It monitors member compliance with those requirements and with the OPTN/UNOS policies. The goal of the Committee’s work is to maintain and improve transplantation quality and safety, as well as member compliance with OPTN/UNOS policies and bylaws and the OPTN Final Rule.

<i>Project Title:</i>	<i>Project Description:</i>
Reassess currency definition used to qualify primary surgeons and primary physicians	Issues continue to be raised by reviewers when assessing transplant program and key personnel applications regarding the definition of currency. A better definition is needed. Currency is inadequately defined in bylaw language.
Quality Assurance and Process Improvement Initiatives (QAPI)	The transplant community has been moving towards more codified and thorough quality improvement initiatives within their organizations. CMS even has requirements for transplant programs to have a quality assurance/process improvement program in place. Based upon the MPSCs review of member compliance and performance, the committee seeks to implement a similar requirement to further enhance OPTN member responsibility in facilitating quality improvement.
Functional Inactivity in Pancreas Programs	In October 2011, the MPSC requested that the Pancreas Transplantation Committee consider modifying the pancreas functional inactivity threshold. The MPSC also requested any additional guidance regarding inactivity in pancreas programs, such as factors to consider when reviewing these programs, or other relevant data. This project is recommended for resurgence based on discussions during the PSR Consensus Conference in February 2012 meeting and the apparent issues revolving around the reliability of the data.

Data Coordination Responsibilities and Guidelines	<p>The project began in 2009/2010, and was delayed based on other work regarding standardized definitions and user guidance. Based upon the recent PSR Consensus Conference, it was recommended this project be reinstated. The OPO Committee previously provided specific bylaw language while the Histocompatibility Committee also made some recommendations during the earlier iteration of the project. The Transplant Administrators and Coordinators committees responded in support, but did not get as far as the other constituency committees. The overall concerns relate to how good is the data, and to improve the data submitted by facilities, there should be some requirements for individuals serving as the data coordinator.</p>
OPTN Bylaws Phase II Rewrite	<p>The bylaws have some provisions that describe processes that are not effective or efficient. Therefore, stakeholders have requested changes. In addition, some provisions need clarification. Finally, some provisions do not reflect actual practices that occur.</p>
Modifications to Functional Inactivity – Inactive Waiting List Requirements	<p>The existing bylaws require patient notification when a program inactivates its waiting list for certain thresholds (15 or more consecutive and/or 28 or more cumulative days in any 365 day period). The bylaws do not require specific content to be included in those patient letters; however, this guidance is available in the OPTN Evaluation Plan.</p>
Composite Pre-Transplant Metrics	<p>Implement metrics for evaluating pre-transplant performance based on risk adjusted SRTR analyses. Intend to identify both over and underperformers, with intent to share best practices with greater community. This metric will identify potential issues with waiting list management practices as well as candidate selection.</p>

<p>Modified Flagging Criteria</p>	<p>Improve the current post-transplant outcome review model used by the MPSC. Potential solutions for exploration: Options include: not changing the existing flagging criteria or adopting parts of the proposed modified flagging algorithm in conjunction with using existing flags. Description of impact on candidates: improving the flagging algorithm for outcome reviews conducted by the MPSC will result in improved outcomes by sharing lessons learned and best practices, in addition it will provide needed assistance to programs that are below expected. In the end, the candidates should have a better experience.</p>
<p>Pancreas Outcome Review – Model Development</p>	<p>Currently the MPSC reviews kidney, liver, heart, and lung transplant programs for one-year post transplant graft and patient survival rates using a statistical analysis produced by the SRTR. In 2006, the MPSC asked the Pancreas Transplantation Committee to review the models available on the SRTR public website to determine usefulness for MPSC evaluation of outcomes in pancreas (including kidney/pancreas) transplant programs. Since that time, the Pancreas Transplantation Committee has been working with the SRTR to improve and/or develop the models to be used by the MPSC.</p>

Minority Affairs Committee (MAC)

The Minority Affairs Committee identifies and considers aspects of organ procurement, allocation, and transplantation with the potential to impact minority populations in particular. The Committee provides input and recommendations regarding ongoing efforts of other OPTN/UNOS Committees and the Board of Directors to ensure that issues and special needs of minority populations are considered and addressed.

<i>Project Title:</i>	<i>Project Description:</i>
Survey on Referral to Thoracic Transplantation	Previous data presented to the ACOT and reviewed by the Committee in 2004 suggested that there may be some delays in minority access to the heart waiting list. The data showed that race and geography may have some impact, but that impact was unclear. The Committee had requested to review the data due to concerns that African Americans were experiencing acute heart failure leading to heart replacement at a later stage than Caucasians. If this was presumed to be true, the Committee also questioned whether or not this would subsequently decrease a patient's chance of being listed because of more advanced disease progression and worse comorbidities.
Minority Donor Conversion Education Project	An eligible donor is defined as an actual donor that meets the eligible death criteria. The conversion rate is defined as the percentage of eligible deaths that became actual donors. The proposed review of data and the development of any resulting educational initiative could potentially address the key goal of increasing the number of transplants if accurate information on donor conversions are communicated to OPO's who could then use the information to measure how well they are performing in terms of converting potential minority donors into actual donors.

<p>Perceptions of the Organ Procurement and Transplantation Network/United Network for Public Comment Period Among Dialysis Patients</p>	<p>The OPTN/UNOS Minority Affairs Committee has been concerned that public opinion on transplant allocation policies does not capture significant minority voices. The committee conducted a survey to ascertain the level of knowledge and understanding of kidney transplantation, allocation policy and the public comment (PC) process among dialysis patients. Survey results did not show that African-Americans had less knowledge about PC than Caucasians. A proposed follow-on activity of this completed committee project is the publication of survey results. The goal of publishing the results is to educate and inform the transplant community and the general public about the importance of patient participation in decisions impacting allocation policy and the importance of tailoring policy messages using communication vehicles that are accessible and preferred by the diverse community of patients.</p>
<p>Referral to Kidney and Liver Transplantation: The Transplant Program’s Perspectives.</p>	<p>This is an educational project which will not follow the policy proposal development process. Abstracts for the Kidney Referral Survey and the Liver Referral Survey have been completed. The Kidney Referral survey has been presented at two national conferences and the Liver Referral survey has been accepted for a poster presentation at ATC this year. Both abstracts are proposed to be developed into a manuscript summarizing survey results.</p>
<p>Comprehensive Review Article: Addressing Issues of Equity and Utility to Enhance Access to Transplantation.</p>	<p>This project is educational in nature and as such would not follow the policy proposal development process. Historical and background information on this project has been compiled.</p>
<p>Establishing Educational Guidelines for Patient Referral to Kidney Transplantation</p>	<p>Many ESRD patients currently undergoing dialysis treatment are medically suitable for transplantation. Data reviewed by the committee has demonstrated that this therapy is often not presented to certain patients or is presented much later in a patient’s disease progression. Ethnic minorities in particular experience disproportionate delays in referral to transplantation as compared to Whites. This committee project proposes the establishment of Educational Guidelines on Patient Referral to Kidney Transplantation.</p>

Operations and Safety Committee

The Operations and Safety Committee (formerly Operations Committee) reviews de-identified transplant and donation-related adverse events and near misses reported to the OPTN in order to identify potential network improvements and revisions to OPTN policies that may prevent future such occurrences. The Committee may develop and recommend specific proposed improvements and policies or it may recommend to the Board that other Committees develop them. The goal of the Committee’s work is to identify gaps in OPTN policy and processes from a network perspective for the purpose of increasing safety.

Project Title:	Project Description:
Develop Policy to Address Waitlist Transfers When Transplant Centers Withdraw Their Membership or Inactive Indefinitely	The Operations and Safety Committee has been asked to lead a joint working group to develop policy to address the process of candidate transfers from centers that have withdrawn their membership or inactivated a program indefinitely.
Organ transportation failures/near misses	The committee seeks to understand the number and types of errors that are occurring related to organ transportation failures/near misses within the transplant community.
Vessel Storage and Disposition Reporting	The committee seeks to reduce the risk of disease transmission to a recipient via the transplant of extra vessels procured from deceased or living donors.
Standardize an organ coding system for tracking of organs	Important information is collected and presented to a center when a donor is identified and organs are allocated. But there is currently no link or traceability of donor risk to all products allocated. How this information is shared, and how recipient and donor variables are analyzed vary from center to center according to local practice.
System for Review of PS Data Enhancements- Improved reporting of safety situations, living donor events, and potential donor derived disease transmission events	The committee seeks to identify trends and patterns of safety events occurring within transplantation to address policy gaps, network improvement and education opportunities for the transplant community.
Development of a Patient Safety Newsletter	The committee seeks to disseminate information to the transplant community regarding safety events reported to the OPTN, adverse events or near misses, to heighten awareness that could lead to improved safety in practice.

Annual Set of Committee Initiatives, 2012-2013

Develop policy to require ABO verification of donor and recipient prior to donor organ recovery and develop a standardized checklist for ABO verification

There are currently no OPTN requirements for ABO verification prior to donor recovery. This regulation under CMS for those centers that are CMS certified. This is a safety issue for those centers that are not CMS certified, as this is currently a CMS requirement but not an OPTN requirement. CMS and OPTN site surveys have identified ABO verification as being the number one policy/regulations that are not consistently complied with in living donor and deceased donor transplant.

Develop policy to ensure accuracy of ABO subtyping

The Committee seeks to enhance the safety of recipients receiving subtype compatible transplants by proposing requirements that would ensure that subtype testing is accurate and reproducible prior to transplant.

Organ Procurement Organization (OPO) Committee

The OPO Committee considers issues relating to organ procurement organizations and their role in increasing the number of organs recovered and placed efficiently and effectively. It considers medical, scientific, and ethical aspects of organ procurement as they pertain to the purview and responsibilities of the OPTN.

<i>Project Title:</i>	<i>Project Description:</i>
Unique identifier documentation requirements	The OPO committee will submit a proposal which will require OPOs and living donor recovery centers to document the locally assigned unique identifiers in the donor record. This will allow transplant centers the ability to validate it. Requiring documentation of unique identifiers provides needed validation information in the donor chart will reduce the possibility of transplant centers not being able to use tissue typing materials because of lack of validation.
Uncontrolled DCD (u-DCD) Model Elements	The subcommittee has developed a survey to determine current practice and to identify whether or not the term “uncontrolled” appropriately describes the process. Setting protocols for uncontrolled DCD recovery could provide a better understanding of the practice and increase the number of organs recovered.
OPO Scorecard Thresholds	The subcommittee agreed to recommend a clinical threshold of 95% but requested more analysis on the administrative score before making a recommendation. This analysis will include the review of the individual components of the score to determine what aspects are leading to the variability in scores. Setting standards for OPOs will provide process improvement that will improve all aspects of organ procurement and allocation and reduce mistakes that could impact patient safety.
Revisions to Policy 5	The committee recognizes the need to clarify policy language regarding requirements for shipment, packaging, labeling, and storage of vessels, organs, and other materials. Policy 5 is an important policy that sets requirements for shipment, packaging, labeling, and storage of vessels, organs, and other materials.

"R" Value Shipping Standards

The OPO Committee tasked the Labeling and Packaging Subcommittee with investigating the subject of R values on containers used to ship organs. (e.g. how the "R" value standard was determined, as well as manufacturer "R" value standards in transport of organs and tissues). In addition to researching the history of the "R" value, the subcommittee will discuss if there is a need to revise current policy regarding the use of "green coolers." Clarification of the proper "R" value and equivalent will promote transplant patient safety and increase the number of transplants. Ambiguity will be removed and member hospitals will have clarity concerning UNOS/OPTN "R" value policy.

Imminent and Eligible (I & E) Death Data

Members are interpreting the imminent and eligible death definitions (defined by policy) differently, which results in inconsistent data reporting.

Pancreas Transplantation Committee

The Pancreas Transplantation Committee is charged with considering medical, scientific, and ethical aspects related to pancreas and pancreas islet organ procurement, distribution, and allocation. The Committee will consider both the broad implications and the specific member situations relating to pancreas and pancreas islet issues and policies. The goal of the Committee’s work is to develop evidence-based policies aimed at reducing the burden of disease in pancreas candidates and recipients, increasing pancreas utilization, improving access to pancreas transplantation as appropriate, and improving the health outcomes of pancreas transplant recipients.

<i>Project Title:</i>	<i>Project Description:</i>
Investigating Sources of Pancreas Discards	Committee members have observed that there are a lot of pancreas allografts discarded for reasons such as surgical error, surgical damage, and poor description of the allograft. Some of this discards may have to do with the experience level of the procuring surgeons, particularly if they are trainees. The Committee would like to investigate these discards. If this is actually a major source of discarded grafts, the Committee would consider interventions such as tying pancreas program certification to availability of procuring surgeons with appropriate training and skill level.
Best Practices for Isolated Pancreas Recovery with an Isolated Intestine Recovery	When an intestine is recovered, the procurement technique used impacts whether the pancreas can be recovered as well. If the intestine procuring surgeon does not leave enough vasculature, an otherwise viable pancreas may not be recovered. Between 2005 and 2009, 280 intestines were recovered from adult donors (410 from donors of all ages). Between 2005 and 2009, only 50 donors (of any age) had a pancreas and intestine recovered for different recipients. The proposed solution is a best practices document or publication that describes the technique to be able to procure both organs.

<p>Review of Facilitated Pancreas Allocation</p>	<p>Improving facilitated pancreas allocation and updating the policy language to align with the way organs are allocated in the DonorNet era could help increase the placement and transplantation of pancreata. The facilitated pancreas language has not been updated since DonorNet was implemented. It is not clear in the policy language whether the goal of the proposal is to increase pancreas placement or to reduce unwanted pancreas offers. The goal of this proposal is to clearly define the purpose of the facilitated pancreas allocation method and to align the policy language to meet this purpose in the DonorNet era.</p>
<p>Defining Pancreas Graft Failure</p>	<p>This project aims to clarify the definition of pancreas graft failure. Its primary impact will be on the validity of pancreas program performance analysis. On many occasions, the Committee has lamented that there is no standard definition for pancreas graft failure. It is current defined as death, re-transplant, re-listing, or reported graft failure. The concern is that transplant centers report graft failures at different points. For example, some programs report a graft as failed if there is any return to insulin therapy whereas other programs only report a pancreas as having failed if insulin use goes above a certain threshold.</p>
<p>Investigating DCD Pancreas Outcomes</p>	<p>Currently, there is sentiment among Committee members that DCD pancreas works well, but there is still not much use of DCD pancreata. An analysis of outcomes could help centers determine when to use DCD pancreata appropriately, which could increase the number of pancreas transplants.</p>
<p>Investigating characteristics resulting in improved PAK outcomes.</p>	<p>Whereas living donor kidney transplant outcomes may be superior to deceased donor kidney transplant outcomes for kidney-alone recipients, the case is more complicated for candidates who need both a kidney and a pancreas. The committee seeks to find out what characteristics result in improved outcomes for PAK recipients.</p>
<p>Review Pancreas Primary Physician/Surgeon Bylaws</p>	<p>The bylaw requirements for primary pancreas physicians and surgeons stands to be reviewed for currency and improvements.</p>

Pancreas for technical reasons	It is not clear how pancreata used for technical reasons should be reported. Transplant centers and OPOs do not always agree on the appropriate disposition code (transplanted or not transplanted) for pancreata that are used for technical reasons as part of multi-organ transplants, so the disposition can be reported differently. This discrepancy in reporting results in data errors.
Islet infusion reporting	Every islet infusion is not being reported to the OPTN.
Implement pancreas allocation system approved by the Board in November 2010	The committee seeks to prepare for the implementation of an efficient, uniform pancreas allocation system approved by the Board in November 2010. This task just includes the effort to implement the new system.

Patient Affairs Committee (PAC)

The Patient Affairs Committee advises the UNOS Board of Directors and other committees about patient and donor family perspectives on OPTN policies and initiatives that originate in other Committees. It may work independently or with other Committees, as approved by OPTN leadership, in the development of initiatives and policy proposals with significant import for topics of interest to patients, including transplant access, outcomes, and safety. The Committee helps develop and provide input on educational OPTN-related information for transplant candidates, recipients, families, and patient groups.

<i>Project Title:</i>	<i>Project Description:</i>
Education Program to Promote Teen Adherence	The Committee has completed a review of the current literature on teen adherence. The Committee has also compiled available OPTN data on graft loss and re-transplant in efforts to define the problem. The Committee has also searched unsuccessfully, for interactive or web-based transplant educational resources that might appeal to teens.
Organ Specific What Every Patient Needs to Know Series	The Committee was asked to provide expert input in developing an organ companion series to “What Every Patient Needs to Know” (WEP). The Committee is interested in collaborating on this project.
Patient Notification Bylaws Reorganization	Patient Notification errors are one of the most cited errors. There are 11 different bylaws which contain some type of patient notification requirement. Among these, there is significant variation in how patient notification is accomplished depending on the rationale for the notification and the patient population being notified. In general, patient notification can be grouped as follows: 1) Wait List Notification 2) Due Process Notification 3) Living Donor Notification 4) Single Surgeon Center Notification Transplant Centers are most often involved with waitlist notification. Transplant Center staff specifically, relate confusion regarding the waitlist notification requirements (Appendix BII Transplant Hospitals, Section F- Patient Notification, Appendix B, Attachment I-XIII; Section 13, Patient Notification) Anecdotally, Transplant Center staff are generally unaware of the full scope of patient notification within OPTN/UNOS Bylaws. Transplant Administrators and Coordinators report difficulty in locating the patient notification requirement specific

<p>to their situation. The use of the word 'letter' in the title of the OPTN Contractor letter further adds to confusion around notification; as Transplant Programs are required to send program-specific letters informing patients of an action taken by, or regarding the Transplant Program. Transplant Administrators and Coordinators also verbalize confusion regarding the language to be used in referencing the OPTN Contractor Patient Information Letter within the Transplant Program Patient Notification Letter. Inadequate language or the failure to make the required reference contribute to the number of citations.</p>

Pediatric Transplantation Committee

The Pediatric Transplantation Committee considers medical, scientific, and ethical issues relating to organ procurement, allocation, and transplantation for pediatric patients. These issues include: pre- and postoperative care, expeditious transplantation of children, and the specific medical, social, and psychological needs of children. The committee considers the broad implications of such issues and deals with these specific issues or situations as needed. The goal of the Committee’s work is to develop evidence-based policies aimed at fostering pediatric candidate access to transplantation and good outcomes for patients (including waiting candidates and living donors) involved in pediatric transplantation.

<i>Project Title:</i>	<i>Project Description:</i>
Pediatric Transplantation Training and Experience Considerations in the Bylaws	Currently, transplant hospitals that predominately serve pediatric candidates may have professionals without ANY pediatric transplant experience approved for key personnel roles (primary surgeon, primary physician) as long as they meet those criteria outlined in the bylaws.
Policy to increase the frequency of split liver transplantation	Those liver candidates less than one have the highest waitlist mortality as compared to other age groups of pediatrics patients and all those that are 18 and older. This is due in part to their inability to get size-appropriate liver offers. Additionally, split liver transplantation has proven to be a safe and effective way of using one deceased donor liver to transplant two candidates on the waiting list; usually a small child and an older teen or adult. Even though split liver transplants expand the pool of donor livers allowing more people to receive transplants and be removed from the waiting list, only about one percent of deceased donor livers are split. In many situations splitting a liver to transplant two patients would not be appropriate; however, it appears that a greater number of deceased donor livers that are split could be realized, and in doing so, likely decrease the waiting list mortality of those infants waiting for a liver.

Revisions to pediatric kidney allocation policy	Pediatric kidney transplantation candidates experience substantial long-term side effects due to dialysis including growth and development delays. These effects are more pronounced for pediatric candidates who experience barriers to transplant (e.g., due to sensitization). The intent would be to include these efforts with the development and implementation of a new kidney allocation algorithm.
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Policy Oversight Committee (POC)

The OPTN/UNOS Policy Oversight Committee reviews developing and proposed policies and Committee initiatives for the purpose of providing input both to the Committees and the Board with regard to some specific perspectives. Those perspectives include the degree to which specific proposals address policy goals outlined in either the National Organ Transplant Act or the OPTN Final Rule and whether initiatives/policies are sufficiently evidence-based, where appropriate. The POC may review developing OPTN policies and initiatives through these and/or other perspectives as the leadership directs. The goal of the Committee’s work is to ensure that OPTN initiatives, regardless of sponsoring Committee, are reviewed and evaluated with a standard set of perspectives and are considered as part of a larger national transplantation system.

<i>Project Title:</i>	<i>Project Description:</i>
OMB Form revisions post-PSR consensus conference	A consensus conference was held in February 2012 to address the program-specific reports (PSRs). Improving the PSRs will potentially provide a better understanding of transplant program performance which will help with performance improvements and allow potential candidates to make a better informed decision about where they go for treatment.
Policy Rewrite Project	Since the inception of UNOS in 1984, OPTN policies have been modified by individual committees and the Board in an effort to meet advancements in transplantation and to achieve the principles and goals set out in the Final Rule. Over time, our national committee system (consisting of 21 committees) has incrementally added to the policies and bylaws governing the transplant network without systematic assessment and planned revisions at set intervals. This process has created a set of policies with dissimilar structures; some overlap with or contradict one another. The policies are not written plainly and their language can confuse readers. Additionally, OPTN/UNOS policies do not state what the policies are intended to accomplish or how the policies will be assessed.

Review multi-organ allocation policies

Multi-organ allocation policies are often confusing to members and contain some ambiguities. What this does is create problems during organ allocation for both OPOs and transplant centers and makes it difficult for compliance personnel and committees/MPSC to identify and adjudicate potential violations. Review the existing policies to see what works and what doesn't and recommend changes. Provide some general recommendations about overarching principles to address important issues such as eligibility, equity, and utility. Potential minimum listing criteria for the various types of multi-organ transplants. This approach would require the most time and effort and could potentially require a significant amount of computer programming.

Thoracic Organ Transplantation Committee

The Thoracic Organ Transplantation Committee considers issues relating to heart and lung procurement, allocation, and transplantation, including medical, scientific, and ethical aspects. The committee also considers the broad implications of such issues and deals with specific individual issues or situations. The goal of the Committee’s work is to develop evidence-based policies aimed at reducing the burden of heart and lung disease in transplant patients (candidates and recipients), increasing thoracic organ utilization, improving access to thoracic transplantation, and improving the health outcomes of thoracic transplant recipients.

<i>Project Title:</i>	<i>Project Description:</i>
Eliminate OPTN designation requirements and status for single heart/lung transplant program	Referred to Thoracic Committee. Chrysalis project’s waitlist team is awaiting the elimination of combined organ transplant single transplant program approval so it can model develop new approach to deal with combined organ transplant cases. The requirements for OPTN designation of a heart/lung transplant program is that it be in a transplant hospital with an OPTN approved heart transplant program and an OPTN approved lung transplant program. The heart/lung is the only example of OPTN transplant program designation for the combined transplant of two distinct organ types with their specific OPTN designation criteria.
Automate the HLA Section in Policy 3.7.12.1.xiii (Human leukocyte antigen (HLA) type if requested by the transplant center)	The intent of automating Policy 3.7.12.1.xii is to enable efficiency in how OPTN Members comply with policy. The Committee seeks to enable secure communication of requests for and provision of HLA typing.
Allocation of Lungs to ABO-Incompatible Candidates	At least one pediatric lung transplant program is willing to transplant children who are able to accept a lung from deceased donor with any blood type. The pediatric lung allocation policy does not permit allocation of organs to ABO-incompatible candidates. The Committees will consider whether or where to place ABO-compatible lung transplant candidates on the lung allocation algorithm. Current policy does not address access to transplant for ABO-incompatible candidates.

<p>24-Hour Downgrade Proposal</p>	<p>The OPTN contractor’s policy evaluation plan requires that heart transplant programs record in UNetSM changes to a heart transplant candidate’s status or criterion within 24 hours, but this requirement is not written in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The two policies state that the OPTN contractor will notify “a responsible member of the transplant team” prior to downgrading a candidate’s Status, but the OPTN contractor does not notify such personnel in addition to displaying the candidate’s status in UNetSM. The proposed modifications include the 24-hour requirement, removal of the notification clause, and edits for plain language. For consistency, the modifications also include language about potential referral of pediatric heart status exception case decisions to the Thoracic Organ Transplantation Committee.</p>
<p>Heart-Lung Allocation (Breaking Ties between Two Heart-Lung Candidates Eligible to Receive the Same Heart-Lung Bloc)</p>	<p>There exists a possibility that two heart-lung candidates, who are in the same geographic area, could be eligible to receive that same set of organs, through a heart or heart-lung match run and a lung match run. Potential Solutions for exploration: 1. Do nothing as this event is rare, if it has occurred at all 2. Change policy to address this circumstance: the OPO should review the total waiting time for the heart-lung candidates that have the highest rankings on the two different match runs and offer the heart and lung to the candidate who waited the longest</p>
<p>Modify Pediatric Heart Allocation Policy</p>	<p>Modify Pediatric Heart Allocation Policy</p>
<p>Revise the Lung Allocation Score (LAS) System</p>	<p>The parameter estimates and the baseline survival rates of the LAS have not been updated since its implementation in May, 2005. The Committee seeks to update these numbers and add new variables in the waiting list and post-transplant models – other variables that predict waiting list mortality and post-transplant survival, in addition to those already in the model – based on the cohort of patients waiting for and in receipt of transplants since May, 2005.</p>

Modify Policy 3.7.3 (Adult Candidate Status) to Better Address the Medical Urgency of Candidates Implanted with Mechanical Circulatory Support Devices (MCSD)

Current policy does not delineate the clinical diversity among candidates implanted with ventricular assist devices (VAD) or MCSDs in general.

Allocation of Deceased Donor Lungs that Have Undergone Ex Vivo Lung Perfusion (EVLP)

It is possible that if the EVLP technology improves, the OPTN may need to be ready to modify the lung allocation system. The Thoracic Committee has already received questions from one member of the lung transplant community about addressing EVLP in lung allocation. Deceased donor lungs that may otherwise be discarded or considered of “marginal quality” may in fact become transplantable due to the fairly new practice of performing EVLP in the US. The United States’ Food and Drug Administration (FDA) has approved several clinical trials related to EVLP. The lung transplant community expects that the FDA will approve EVLP-related instruments for use in the US in 2012. EVLP has the potential to improve the quality of a deceased donor lung, and this has been demonstrated in Canada. The potential use of EVLP by transplant programs and OPOs raises data collection, allocation, and medical judgment questions. EVLP could increase the number of deceased donor lungs that become available for transplant, resulting in an increase in the number of transplants.

Transplant Administrators Committee (TAC)

The Transplant Administrators Committee considers issues related to the administration of transplant programs and provides input to other Committees and the Board with regard to the potential impact of developing policies and other OPTN requirements on transplant program operations. Through non-OPTN resources provided by UNOS as available, the Committee develops initiatives and tools that foster effective transplant program administration (e.g., the annual UNOS Transplant Management Forum, the transplant program staffing survey, and the standardized payer Request for Information (RFI) tool).

None

Transplant Coordinators Committee (TCC)

The OPTN/UNOS Transplant Coordinators Committee, largely comprising both procurement and transplant coordinators, considers issues related to the coordination of efforts related to organ procurement, organ allocation, and the entire transplant process. It also considers the potential impact of proposed policy and bylaws revisions upon the process of procurement and transplant coordination, including the education and care of candidates, recipients, living donors, and families. The goal of the work of this Committee is to improve the quality, efficiency and effectiveness of procurement and transplant coordination through OPTN initiatives and policies.

<i>Project Title:</i>	<i>Project Description:</i>
<p>Pre-Donation Educational DVD for potential Living Donors and those healthcare professionals involved in their evaluation, transplant and follow-up care.</p>	<p>With the increased OPTN focus on living donor safety, there has been an increase in the depth and breadth of OPTN requirements related to living donor transplantation, particularly in the area of informed consent. Additionally, as requirements of the OPTN KPD Program are incorporated into policy language, there are additional informed consent requirements that relate to OPTN processes. Transplant professionals, including members of the KPD Work Group, have requested that the OPTN provide resources, including an educational DVD and documentation templates, to help centers comply with the large volume of informed consent requirements. The proposed DVD would cover all the requirements for living donors found in policy. Transplant centers could use this DVD to help to educate staff or potential living donors. Some centers have similar resources, including one developed by the ASTS. The DVD will include an overview as to what to expect in the living donation and kidney paired donation processes with a focus on the new OPTN requirements for living donation and KPD. More specifically, the DVD will demonstrate healthcare professionals highlighting the importance of the new OPTN regulations/requirements with potential living donors to include safeguards in place and why federal oversight now exists for living donors. The format may also include information and/or questions presented by patients, such as actual or potential living donors. Both format and content will be developed by professionals with instructional, media production, and clinical transplant expertise.</p>

TIEDI Enhancements	The Committee would like to enhance existing Tiedi documentation by providing:
	<ul style="list-style-type: none">• Clarifying definitions for data elements and making them more specific.• Providing guidance as to possible locations in the patient chart for obtaining the information.• Providing guidance as to how to choose between multiple values in a patient chart. Providing examples where appropriate.
Improve communication with candidates about inactive status on waiting list	As the Waitlist grows each year, so does the number of Status 7 (inactive) candidates on the Waitlist. There are various reasons a candidate may to be listed on the Waitlist as a Status 7. Many times, the candidate is not aware that they have been downgraded or initially listed as a Status 7. As such, there is a great need to identify best practices and subsequently educate the community on these practices, timing and communication related to listing and managing candidates.
Release of recipient information	Currently, many transplant centers will not release any or only a scant amount of recipient information to OPOs to provide to donor families. Donor families, after providing their gift, want to have some information about the recipient. OPOs report that the sharing of this information enhances the donation experience for the donor family. The goal is to standardize and ensure “appropriate” information sharing practices between Transplant Hospitals and OPOs regarding recipient feedback to donor families. The Committees wants to provide guidance regarding the standard minimum amount of recipient information (i.e. type of work, parent, child, quality of life, etc) that should be provided to donor families.