

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Annual Set of Committee Goals 2011-2012

Table of Contents

Background	2
OPTN Vision Statement and Key Goals	3-4
General Committee Guidance	5
Annual Goals for 2011-2012	5
Charge and Work Plans by Committee	
Disease Transmission Advisory (Ad Hoc)	6
Ethics	7
Histocompatibility	8
International Relations (Ad Hoc)	9
Kidney Transplantation and KPD Workgroup ..	10-11
Liver and Intestinal Transplantation	12-13
Living Donor	14
Membership and Professional Standards.....	15-16
Minority Affairs	16-17
Operations	17
Organ Procurement Organization.....	18
Pancreas Transplantation	19
Patient Affairs	20
Pediatric Transplantation.....	21
Policy Oversight	22
Thoracic Organ Transplantation	23
Transplant Administrators	24
Transplant Coordinators	25

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:

- Increasing the number of organs transplanted
- Supporting live donor transplantation
- Consideration of net benefit as applied to organ transplantation
- Differences in the opportunity for transplant within the U.S., and
- 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.

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.

OPTN Key Goals and Related Indicators

Increase the number of transplants

- # of Deceased Donors
- # organs transplanted per donor
- % recovered organs not transplanted (discards)

Increase access to transplants

- Transplant rate (overall and by geographic / demographic category)
- WL mortality rates (overall and by geographic / demographic category)
- Comparison of WL/recipient demographics (overall and by geography)
- # listed/ # ESRD (kidney) (overall and by geography)
- Offer rates (overall by geographic / demographic category)

Improve post-transplant survival

- patient survival
- graft survival
- retransplant rates (overall and by organ within x years)
- Rates of death with a functioning graft (kidney/liver)

Promote transplant patient safety

- post-transplant complication rates
 - o primary graft non-function
 - o patient death rates less than 30 d.
- other adverse events, including unintended ABO incompatibilities
- disease transmission rate (proven or probable)
- # programs/members that get MPSC adverse actions (letter of reprimand or more severe)
- # transportation mishaps/near misses

Promote living donor safety

- # living donor deaths within 90 days
- post-surgical complication rates (pick 1 or 2)
- % kidney donors on dialysis, short and long-term (from available sources of information)
- % (kidney and liver donors) placed on WL
- # misdirected LD organs
- Lost to follow up rates
- # programs/members that get MPSC adverse actions (letter of reprimand or more severe) for LD policy/bylaw violations

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.

Annual Committee Goals for 2011-2012

The Annual Committee goals that follow for 2011-2012 are intended to further the OPTN's work in at least one of the 5 key challenge or Strategic Focus areas and to guide the Committees in the prioritization of the work they undertake during the coming year. Committees are to focus on these 67 activities first and add new ones with the approval of Board leadership.

Committee Charge and Initiatives for 2011-2012

(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.

1) Proposed Minimum Screening Requirements for Potential Living Donors

There are currently no policy requirements for screening potential living donors, only guidance documents developed by the Living Donor Committee. The DTAC shared recommendations regarding minimum screening requirements with the Living Donor Committee in June 2010, and will move forward, using its testing expertise, in proposing policy language related to these recommendations.

2) Guidance for Considering Donor with Meningoencephalitis of Unknown Etiology

The DTAC has recognized a trend in recipient adverse outcomes when organs from donors when death involved meningoencephalitis (defined here are meningitis or encephalitis) of unknown etiology. The Committee has recognized that Non-bacterial meningoencephalitis in the donor is highly associated with transmission to recipients and high morbidity and mortality. The Committee wishes to call both OPO and transplant program attention to this area of concern by putting together a guidance document for those evaluating donors with potential meningoencephalitis and also those considering organ offers or treating recipients who received organs from this patient population.

3) Bi-annual DTAC E-Newsletter

The Committee launched its newsletter in 2010. It has proven to be an effective communication tool for educating members and sharing tips or points of interest learned by the DTAC during its review of aggregate data on donor-derived disease transmissions.

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

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. DTAC will focus specifically on the disease transmission reporting page.

5) OPO Screening Practices Survey

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.

Ethics Committee
<p>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.</p> <p>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>

- 1) Work with policy writing committees at early stages in policy development to identify and discuss potential ethical issues related to the policy topics.

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.

1) Update Calculated Panel Reactive Antibody (CPRA)

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. Based on post-implementation data 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. These revisions should include updating the HLA frequencies used to calculate CPRA, the addition of the antigen C to the calculation, and the CPRA defaulting to 0.

2) Develop guidelines and mechanisms to utilize the HLA discrepant typing reports and HLA typing data from the match run and from the donor and recipient histocompatibility forms in order to ensure that all discrepancies in HLA typing are resolved so that analyses of the data for use in determining allocation policies and for research purposes use the most accurate data available. Flagging of HLA discrepancies could also serve as a patient safety check, especially with the advent of CPRA.

3) Monitor CPRA

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.

4) Rewrite of the Histocompatibility standards within OPTN/UNOS Policy and Bylaws

5) Collaborate with the Kidney and Pancreas committees to:

- a. Oversee implementation of a sliding scale for sensitization points awarded for CPRA in the new kidney/pancreas allocation system
- b. Develop tools for dealing with candidates who have undergone desensitization with the kidney and thoracic committees

(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.

1) **Audit Transplant Programs that Transplant More 5% Non-Resident Aliens due to Deceased Donation**

Assess and evaluate the reasons a transplant program may have for transplanting more than 5% non-resident aliens due to deceased donation. The evaluation is for each organ transplant program. The rationale for this audit is due to its prescription in Policy 6.3 (Audit).

2) **Evaluate and Revise Policy 6.0 (Transplantation of Non-Resident Aliens) for Currency**

Policy 6.0 addresses a variety of concepts, not all of which may need to remain in 6.0 or remain as policies. Some of the policies in 6.0 cannot be monitored as written. The policies that define residency status do not include those candidates who are undocumented. Importation and exportation of organs are in one policy section and are not related to the transplantation of non-resident aliens. Policy 6.3 (Audit) poses concerns for the transplant community, because anecdotal data suggest that transplant programs consider not transplanting candidates who are non-resident aliens to avoid an audit. Further, Policy 6.3 is vague on the consequences of the audit. Policy 6.0 addresses valuable consideration, but recovery and transplantation of organs for valuable consideration is prohibited in the United States – unrelated to transplantation of nonresident aliens. Policy 6.0 does not address transplant tourism as it occurs in the living donation process.

UNetSM collects citizenship of deceased and living donors, as well as transplant candidates. However, the definition of citizenship and non-resident alien in policy differs from what is presented in UNetSM. The citizenship data collected are: citizen; resident alien; and, non-resident alien. The number of documented non-resident aliens as well as undocumented non-resident aliens is likely underrepresented in the OPTN database, because these individuals – given their intent to reside in the United States – are more likely to self report as a citizen or a resident alien.

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.

- 1) Redesign the OPTN Deceased Kidney Allocation System to improve the effectiveness and efficiency of the system, and increase the total number of life-years gained by transplant recipients.

- 2) Kidney Allocation Variance Reform

Almost every OPO in the country has at least one variance to the national kidney allocation system. These variations lead to difficulties and increased expense associated with maintenance. Additionally, some of these variances have been in place for decades and have not been reviewed/modified to account for advances in medical practice.

- 3) Kidney Waiting Time Modification

Policies addressing waiting time modification are not clear, leading to wasted time for transplant centers submitting requests, for UNOS staff processing requests, and for the Kidney Transplantation Committee reviewing requests. Required documentation is often missing and results in delays for transplant candidates to receive additional time that they are entitled to under OPTN policy. The Committee would like to see fewer submissions of incomplete requests and faster time to implementation of waiting time modifications.

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.

1) Implement KPD Automated Solution

The Board of Directors approved an automated solution for KPD in June 2008. The intent of the manual solution was to be a limited implementation of the OPTN KPD Pilot Program to help staff gain experience before rolling out a national system. The automated solution will be integrated with UNetSM and will be available to any program approved to perform living donor kidney transplants once the system is fully implemented. The automated solution will address all the above limitations of the manual solution.

2) 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.

3) 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.

4) Updating KPD Educational and Financial Materials

The KPD Work Group would like to continue to refine and revise the educational materials and financial best practices as necessary to keep them up to date throughout the OPTN KPD Pilot 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.

1) Ongoing review of MELD/PELD Exceptions

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. The number of exceptions is also an indication of how MELD/PELD is working, i.e., how many patients are served by their MELD scores. The Committee may wish to add to the list of 'standard MELD exceptions' and/or renew the discussion about a National Review Board.

2) Ongoing review of Status 1A/B Cases not meeting criteria

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. At present, the committee plans to continue using the process implemented in August 2010, but to monitor its efficacy.

3) Enhancements to the MELD score / Liver Allocation

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.

4) Additional Priority for DCD Recipients That Require Retransplant

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).

5) Allocation of livers for hepatocyte transplants

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.

6) Further development of policies to reduce geographic disparities in waiting list mortality

In June 2010, the Board approved the following: RESOLVED, that the Liver and Intestinal Organ Transplantation Committee shall be charged with making recommendations to reduce geographic

disparities in waitlist mortality.

7) Facilitated placement / reduced discards

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 also interested in identifying factors associated with discard in hopes that better education may reduce discard.

8) Develop minimum listing criteria for simultaneous liver/kidney transplants

9) Criteria for Intestine Surgeons and Physicians

There are no criteria for intestine transplant surgeons and physicians, despite the fact that this practice has been growing. The Committee has drafted criteria that are based on the liver transplant surgeon and physician criteria, but tailored to accommodate the smaller numbers of intestine transplants performed annually.

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.

1) Guidance for Living Donor Advocates

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. The Committee wishes to develop a set of recommendations for IDA's similar to the consent and medical evaluation a resource the Living Donor Committee has previously developed.

2) Develop Living Donation Consent Policies

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.

3) Develop Policies for the Medical Evaluation of Living Donors

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.

4) New Requirements for the Transport of Living Donor Organ

Current policies for the packaging and shipping of deceased donor organs are being proposed for living donor organs through the public comment process. The Committee has been asked to consider if new policies for the transport of living donor organs are needed. Specifically, if standardization for how living donor organs are shipped throughout the country may be required.

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.

1) Pancreas Outcome Review – Model Development

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.

2) Modified Flagging Criteria

Improve the current post-transplant outcome review model used by the MPSC.

3) Composite Pre-Transplant Metrics

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.

4) Modifications to Functional Inactivity – Inactive Waiting List Requirements

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.

5) Unique Organ Transplant Program Designation for each Transplant Hospital Facility in which Organ Transplant Surgery is Performed

Maintaining transplant program data collection and performance analysis integrity at a transplant hospital level (surgical facility) so the each program is reviewed in a distinct manner regardless of the overall institutional management governance. This is a requirement of the OPTN contract.

6) OPTN Bylaws Phase I Rewrite

Difficult to read and use current OPTN Bylaws will be reorganized and rewritten. The revised Bylaws will be rewritten in clearer and more concise language and have features that make it more usable, including a table of contents, index, headers, footers, larger font size and better headings.

7) OPTN Bylaws Phase II Rewrite

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.

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.

1) Establishing Educational Guidelines for Patient Referral to Kidney Transplantation

This committee project proposes the establishment of Educational Guidelines on Patient Referral to Kidney Transplantation to:

- a. Better define who is an appropriate transplant candidate by including suggested absolute and relative contraindications to transplant.
- b. Establish the optimal timeframe for patient referral with examples (emphasizing that referral is a continuous process with annual reassessment)
- c. Emphasize the benefits of transplantation preemptively and in general from a fiscal and societal perspective.
- d. Share these understanding with the community of referring physicians/ESRD providers through written guidance promoted through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKDOQUI).

2) Comprehensive Review Article

3) Survey on Referral to Liver Transplantation

The committee developed an online Survey on Referral to Liver Transplantation to explore barriers to liver referral and wait listing for different ethnic groups. The initial online survey questionnaire targeted transplant centers and was modeled after the Survey on Referral to Kidney Transplantation. The survey was distributed and has now closed. A second phase of the survey project would involve a more targeted survey of referring providers for ESLD (including hepatologists, gastroenterologists, oncologists, etc.) to determine overall criteria these physicians use to determine when a patient with ESLD would be referred for transplant evaluation. This second questionnaire would target these providers through newsletters and websites of professional

organizations and other communication vehicles. The committee is considering publishing the results of both surveys in a professional journal article.

4) Referral Survey Article

Over the past several years, the committee has been examining possible factors related to lower referral rates and delays for minority patients gaining access to the kidney waiting list. The committee proposes publication of a journal article detailing survey results to educate and inform the transplant community about the need for more standardization and oversight in this area.

5) Perceptions of the Organ Procurement and Transplantation Network/United Network for Public Comment Period Among Dialysis Patients

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. 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.

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.

1) Develop appropriate 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.

1) Imminent and Eligible (I & E) Death Definition

Members are interpreting the imminent and eligible death definitions (defined by policy) differently, which results in inconsistent data reporting. The current HRSA contract requires that the OPTN collect patient level data for all imminent and eligible deaths. It is anticipated that patient level reporting of eligible deaths will allow for better performance modeling. The Committee agrees that the definitions of imminent and eligible death must be clarified in order to make the reported data consistent and valuable.

2) Develop electronic tracking of organs for transport

The Committee is investigating the use of current technologies (i.e. bar coding) that may be available to track shipped organs more effectively and decrease the number of organs wasted.

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.

- 1) Implement the Pancreas Allocation System (approved by the Board in November 2010) that will increase utilization of the pancreas, increase access for SPK and PA candidates, reduce waiting time for all pancreas candidates without adversely affecting adult and pediatric renal transplantation candidates, and reduce geographic inequities of access and waiting time.

- 2) 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.

- 3) Review Pancreas Primary Physician/Surgeon Bylaws

The bylaw requirements for primary pancreas physicians and surgeons stands to be reviewed for currency and improvements.

- 4) Report Islet Infusion

There is currently no OPTN tracking of islets once they have been infused. There is a mechanism for report islet infusions in UNetSM, it is just not required in policy.

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.

1) Patient Notification Bylaws

Propose a reorganization of OPTN bylaws to make patient notification requirements more accessible and understandable, with the goal of increasing member compliance with existing requirements.

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.

1) 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.

2) Policy to increase the frequency of split liver transplantation

The committees are considering modifying the liver allocation algorithm so that pediatric candidates less than a certain to be determined age (infants) would receive a higher priority on the match run for certain aged donors (also TBD).

3) Addition of Pediatric Transplantation 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. The Committee wishes to explore including language mandating that key personnel at transplant centers predominately serving pediatric candidates have some experience with pediatric transplantation or establish specific criteria regarding pediatric transplantation for those key personnel at transplant centers predominately serving pediatric candidates

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.

- 1) Provide early feedback to committees and advice to the Executive Committee on the development of policy proposals.
- 2) Review new policy proposals for adherence to organizational priorities.
- 3) Oversee ongoing policy rewrite project – provide input regarding clarity and quality of rewritten and reformatted policy language.
- 4) Multi-organ allocation policies – establish a working plan for gathering information about the principles for multi-organ allocation, seek input from various committees about how to apply the principles to modify existing policies, and move forward with specific policy proposals from each committee based on the principles.

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.

1) Breaking Ties between Two Heart-Lung Candidates Eligible to Receive the Same Heart-Lung Bloc

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. The Committee seeks to determine possible solutions for breaking ties.

2) Revise the Lung Allocation Score (LAS) System

3) Modify Pediatric Heart Allocation Policy

The Committees believe that pediatric waitlist mortality can be improved. Pediatric heart status categories were developed to minimize the role of waiting time in pediatric heart allocation so that hearts from pediatric donors would be offered first to those most urgent candidates. Currently, a significant number of pediatric candidates are listed as Status 1A, which has resulted in the system reverting back to one that is again highly dependent upon waiting time as it is used as a tie-breaker when there are multiple candidates in the same match run classification. In addition, further development of ABO-incompatible heart transplant policy, including allocation to appropriate in utero candidates, needs to be considered.

4) 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.

5) Develop a Simple, Bilirubin Calculator

Elevations in bilirubin levels are indicative of right heart failure. The Board approved the addition of current and increase in bilirubin to the LAS in 2009; however, this variable has not been implemented in the LAS system. The lung transplant community caring for candidates in Group B – primarily patients diagnosed with pulmonary hypertension – wish to apply the bilirubin policy long before the revised LAS is implemented.

6) Create a Form to Standardize ABO Verification Process Performed at Donor Hospitals

The Committee seeks to standardize ABO verifications performed at donor hospitals.

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).

- 1) Develop educational strategies for members regarding more effective use of DonorNet®, including development of standardized definitions and improved documentation and also develop a glossary of abbreviations for DonorNet® use.

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.

1) 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 Committee 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.

2) 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 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.