



ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Annual Set of Committee Goals and Progress Report 2014-2015

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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 2005 and has evolved over time. Committees have been developing annual work plans for several years but this new process includes one additional step—prioritization. The goal of the 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. The vision and priorities of the organization were codified in the 2012 OPTN Strategic Plan.

OPTN Vision Statement

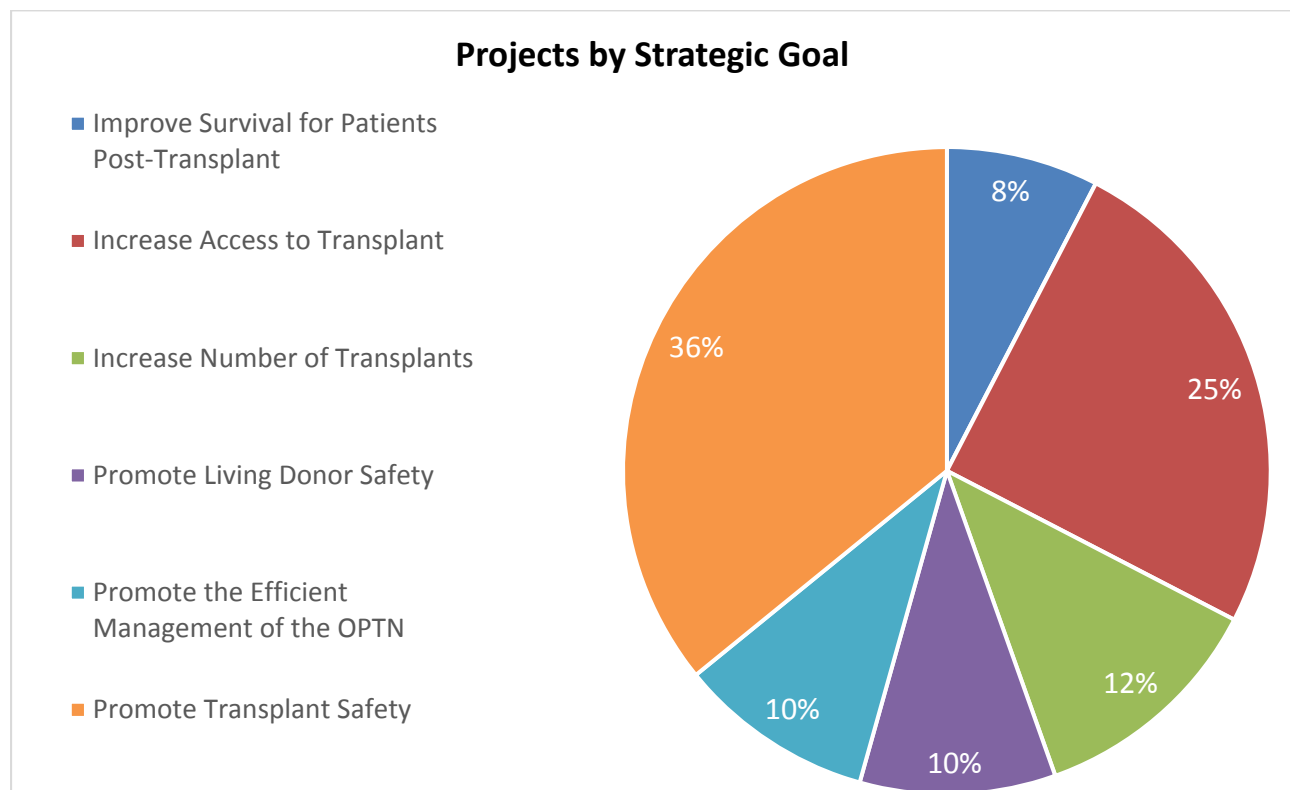
The OPTN promotes long, healthy, and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation; and doing so by balancing competing goals in ways that are transparent, inclusive, and enhance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

OPTN Key Goals

At its meeting on June 25-26, 2012, the Board adopted 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.

Committees must explain how their project supports the OPTN Strategic Plan. Many projects support more than one key goal. The following chart indicates the percentage of the 2014-2015 committee projects that support each of the six key goals.



The projects listed in this report were submitted by the committees to the Policy Oversight Committee (POC). The POC reviewed the project proposals for their alignment with the OPTN Strategic Plan, the strength of the project plans, and available resources. Staff estimated the level of effort necessary to complete the proposals and combined those estimates with the POC's recommendations and priorities from Committee chairs to develop a committee project workplan. The Chair of the POC then presented this portfolio of committee projects to the Executive Committee at their meeting in Richmond, VA on June 23, 2014. The Board of Directors has the ultimate authority for approving the overall OPTN workplan. The below projects are those proposals that were approved by the Executive Committee.

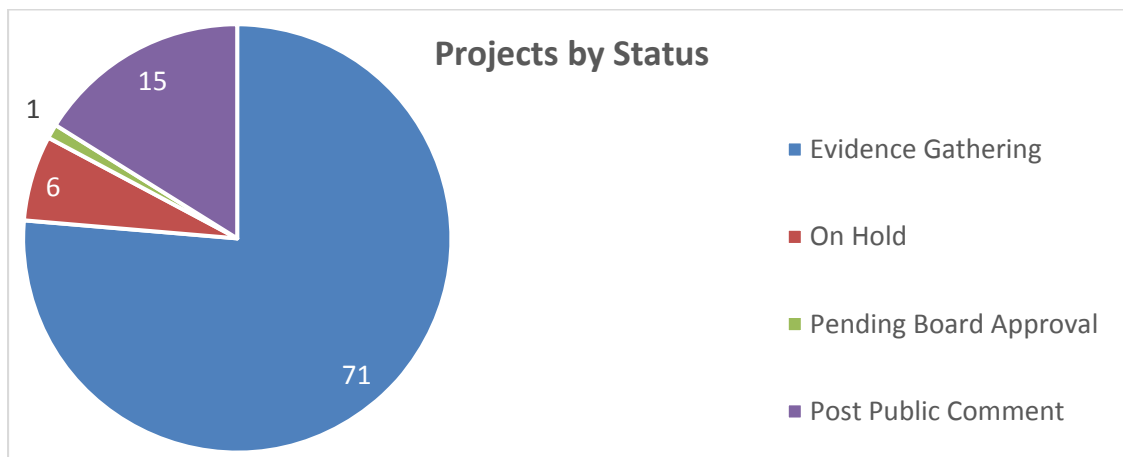
Committee Project Process

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, or the Executive Committee may be able to approve documents or activities of the Committee between Board meetings.

Committee projects go through several phases of development and not all projects will result in a final proposal recommending a change to the system. A successful project could be one where the Committee recommends maintaining the status-quo. The below report references the following project statuses:

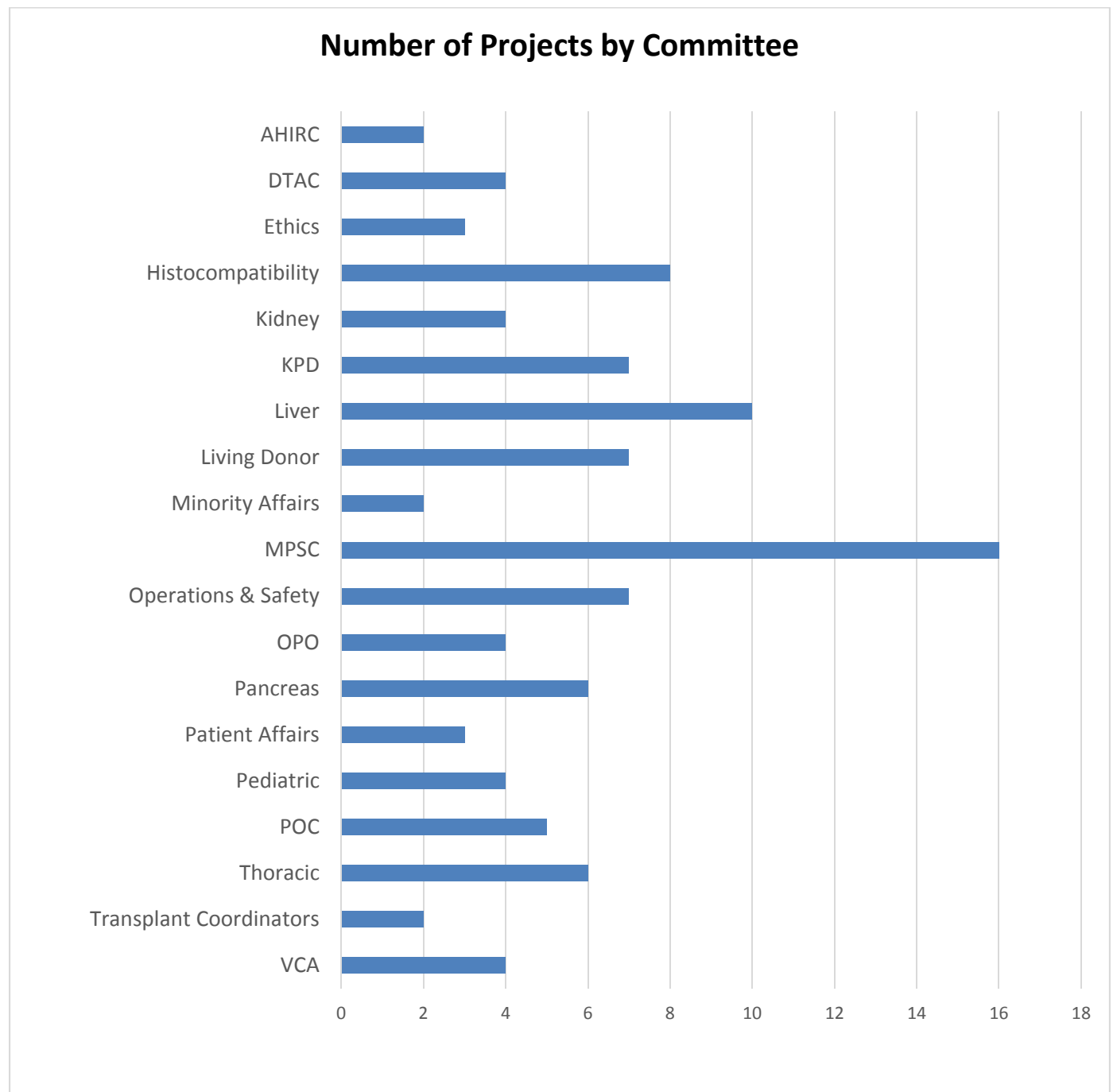
- *Evidence Gathering*: These are active project that have not yet been released for public comment. The Committee is reviewing evidence regarding the stated problem and possible solutions. The Committee might be discussing possible solutions with other Committees.
- *Public Comment*: These projects have been approved by the Executive Committee for public comment. Projects that require public comment are policy & bylaw modifications and new data collection.
- *Post-Public Comment*: The Committee is reviewing feedback collected during public comment.
- *Pending Board Approval*: These projects did not require public comment. The Committee has settled on their preferred solution and is preparing their proposal for Board consideration. Projects that don't require public comment include guidance documents.
- *On Hold*: The Committee does not currently have the resources or this project is not currently a top priority for the Committee, but the project has merit and will be revisited at a later date.

The following chart indicates the percentage of the 2014-2015 committee projects at each stage.



Committee Projects for 2014-2015

The Committee projects for 2014-2015 were approved by the Executive Committee to further the OPTN's work in at least one of the six key goals and to guide the Committees in the prioritization of the work they undertake during the coming year. The project count for each Committee is provided below, followed by a summary listing of project titles by lead sponsoring Committee. Finally, comprehensive details and updates notes are provided for each project.



Ad Hoc Disease Transmission Advisory

2013 PHS Guideline Review
Donor Screening Guidance for Seasonal and Geographically Endemic Infectious Diseases
Modifications to How New Donor Information Received Post-Transplant is Reported to Recipient Centers
What to do when serologies affecting match run appearance are updated

Ad Hoc International Relations

Define "Exhausting the Match Run"
Review Deceased Donor Import Policy

Ethics

Ethical Considerations of Imminent Death Donation
Review Existing White Papers for Accuracy and Relevancy

Histocompatibility

Addressing HLA Typing Errors
CPRA Manuscript
Enhancing Prioritization for DR Matching in Deceased Kidney Donor Allocation
Expanding HLA Typing Requirements
Histocompatibility Bylaws Rewrite: Phase 2
Histocompatibility Testing Guidance Document

Histocompatibility; Kidney

Changes to KAS: CPRA and priority for patient's undergoing desensitization

Kidney

Addressing Geographic Disparities in Deceased Donor Kidney Allocation
Develop national standard for marking organ laterality
Simultaneous Liver Kidney Allocation

Kidney Paired Donation

Allowing Deceased Donor Chains in the OPTN KPD Pilot Program
KPD - All Other Guidelines to Policy
KPD Histocompatibility Guidelines to Policy
KPD Informed Consent Guidelines to Policy
Membership Requirements for KPD Centers
Revising KPD Priority Points

Liver and Intestines

Cap HCC Exception Score @ 34
Changes to Criteria for Auto Approval
Delay HCC Exception Score Assignment
Develop materials to educate RRB members / promote consistent review of exceptions
Liver Distribution Redesign Modeling (Redistricting of Regions)
National Liver Review Board

Ongoing review of MELD/PELD Exceptions

Liver and Intestines; Membership & Professional Standards

Criteria for Intestine Surgeons and Physicians

Liver and Intestines; Pediatric

Revisiting the PELD Score

Living Donor

Clarify Status of Domino Donors

Guidance Document Addressing Abnormal Lab Results During LD Follow-up

Improve Reporting of Aborted Procedures and Non Transplanted Organs

Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors

Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors

Require Reporting of Aborted Living Donor Organ Recovery Procedures

Living Donor; Operations & Safety

New Requirements for the Transport of Living Donor Organs

Membership & Professional Standards

Approved Transplant Fellowship Training Programs

Composite Pre-Transplant Metrics

Consider multi-organ procurement requirement for primary surgeon criteria

Consider primary surgeon qualification - primary or first assistant on transplant cases

Consider requirement for primary physician observation of procurements

Data Submission Accuracy and Supporting Documentation

Define "working knowledge" for primary physician qualification pathways

Definition of a Transplant Hospital

Evaluate Foreign Board Certification Bylaws for Primary Surgeons & Physicians

Geographical Isolation BOD consideration

Primary Physician specialty & subspecialty board certifications

Primary Surgeon Procurement Requirement

Quality Assurance & Process Improvement Initiatives

Reassess currency requirements for primary surgeons and primary physicians

Minority Affairs

Guidance on Informed Consent for Living Donors Representing Vulnerable/High Risk Populations

Minority Affairs; Patient Affairs

The Patients Guide to Referral to Kidney Transplantation

Operations & Safety

Clarify requirements for blood type verification and align with CMS regulation where possible

- Develop Policy to Address Safety Concerns Related to Large Volume Waitlist Transfers
- Develop system for review and sharing of safety events reported through multiple portals at UNOS
- Infectious Disease Verification Process to Enhance Patient Safety
- Modify or eliminate internal vessel label
- Patient Safety Newsletter
- Standardize an organ coding system for tracking of organs

Organ Procurement Organization

- Deceased Donor Registration Form Completion
- HIV Organ Policy Equity Act Planning
- Limit Paper Documentation Required to be included with Organ Packaging

Pancreas

- Define Pancreas Graft Failure
- Pancreas as a Part of a Multivisceral (formerly "Pancreas for technical reasons")
- Pancreas Underutilization
- Require the collection of serum lipase for all pancreas donors
- Review Pancreas Primary Physician/Surgeon Bylaws

Patient Affairs

- Clarify Policy Language and Process for Individual Wait Time Transfer
- Pediatric to Adult Care Transition Project
- Update 'What Every Patient Needs to Know' Brochure

Pediatric

- General Principles for Pediatric Allocation
- Pediatric Classification for Liver Allocation
- Pediatric Transplantation Training and Experience Considerations in the Bylaws

Policy Oversight

- Clerical changes to policy
- Definition of the End of a Transplant
- Geographical Disparities in Organ Allocation
- Multi-Organ Allocation
- Policy Rewrite Parking Lot- Quick Fixes

Thoracic

- Allocation of Deceased Donor Lungs that Have Undergone Ex Vivo Lung Perfusion (EVLP)
- Collect ECMO Data at Removal for Lung Candidates
- Heart-Lung Allocation
- Modification of the Heart Allocation System
- Pediatric Lung Allocation Policy Review

Transplant Coordinators

- Proposal to Notify Patients Having an Extended Inactive Status
- Tiedi Enhancements

Vascularized Composite Allograft

VCA database

VCA Donor Authorization

VCA Membership Requirements

VCA Organ Definition

2013 PHS Guideline Review

Sponsoring Committee

Ad Hoc Disease Transmission Advisory

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

The PHS released a new Guideline meant to reduce opportunity for transmission of HIV, HBV, and HCV in organ transplant on June 19, 2013. This document supersedes the 1994 Guidelines used by the transplant community to determine "high risk" donors. The new Guideline offers more specific categories for identifying donors at increased risk for disease transmission during the medical/social evaluation, but also includes specific recommendations regarding testing of donors (living and deceased) as well as pre- and post-transplant testing of recipients and specimen storage. This document needs to be carefully reviewed to determine whether some of these new recommendations should be incorporated into OPTN Policy, or remain as recommendations for the transplant community. The Executive Committee has already approved modifications to current policy references to the PHS Guideline in order to address confusion in the OPO Community regarding medical-social evaluation questions. This effort is meant to address the balance of the document.

Progress To Date

Joint subcommittee met and named group leaders to review assigned groupings of recommendations. They looked over the DTAC's recommended changes to address references to the PHS Guideline in current policy related to med-soc evaluation of donors to determine increased risk for blood-borne disease transmission. The Executive Committee approved the standardization of the terminology at their August, 27th meeting. The Board set a final transition date at their November meeting. The workgroup met several times to review which portions of the PHS Guideline should be incorporated into OPTN/UNOS policy. The Committee reviewed working group feedback in December 2013. Consensus was reached on all issues with the exception of HCV NAT for all donors. In January 2014, the Committee voted in support of taking proposal out for March 2014 public comment in January 2014. Internal reviews were completed and the document went to the POC for consideration in February. In Feb. 2014, the POC approved public comment proposal release. In March 2014, the Executive Committee approved public comment proposal release. For April 2014, public comment has been favorable to date across regions, committees, and individuals. Very little feedback has been received regarding questions outlined on "at a glance" page. Internal committee team met 5/1. To date, feedback remains favorable. The OPO Committee is convening a subcommittee to review specific questions included in the at-a-glance box. May 2014: Regional feedback, specifically related to proposed mandatory HCV NAT for all donors, is beginning to create some discussion and disagreement within the regions. The Committee anticipated this and welcomes the feedback, as clear agreement could not be reached within the Committee or even the larger Joint Subcommittee on this topic. June 2014: Public comment period has closed. Feedback is mostly favorable, but questions are focused upon HCV NAT for all donors and how to address potential false positives in a timely manner. The Committee will consider feedback during its August 2014 meeting. July 2014: Briefing paper is in development, bringing all comments together for committee review and response.

Possible Solutions

Policy Solution

Four subgroups are actively met to review each of the 30+ recommendations laid out in the new Guideline. Modifications to Policies 2.2 (OPO Responsibilities); 2.4 (Deceased Donor Medical and Behavioral History); 2.7 (HIV Screening of Potential Deceased Donors); 2.9 (Required Deceased Donor Information); 14.4.B Living Kidney Donor Medical Evaluation Requirements; 15.3 (Informed Consent of Transmissible Disease Risk); 15.3.A (Deceased Donors with Additional Risk Identified Pre-transplant); 15.3B (Deceased Donors at Increased Risk for Blood-borne Pathogens); 16.7.B (Vessel Storage) are proposed.

IT Solution

Any policy modifications pursued are expected to impact DonorNet and living and deceased donor data collection forms.

Instructional Solution

Education regarding these changes will be critical to success. The transplant community is unclear on requirement to follow the guideline. Current policy only includes requirement to use medical-social evaluation questions when considering potential deceased and living donors. It does not include requirements for donor and recipient testing, specimen collection and storage, etc. as outlined in the new document.

Other Solution

Guidance documents may be more appropriate than policy requirements in some instances. This is one route being discussed within the Joint Subcommittee.

Donor Screening Guidance for Seasonal and Geographically Endemic Infectious Diseases

Sponsoring Committee

Ad Hoc Disease Transmission Advisory

Public Comment: N/A

Board Date: 2014-November

Status Evidence Gathering

Problem Statement

Recently implemented living donor screening requirements for West Nile Virus, Strongyloides, and Chagas have proved challenging for transplant centers, who are asking for assistance in developing a protocol for this required screening. Specifically, they are asking for help defining "endemic areas" as referenced in Policy 12.3.4 (J). Subsequent living donor policy recommendations to eliminate the requirement for these three specific diseases in favor of more general requirements for living donor programs to develop their own protocols for identifying potential living donors at risk for seasonal or geographically endemic diseases will be released for public comment in Spring 2014. This document will be a resource to programs as they develop these requirements.

Progress To Date

2012-2013: Subcommittee formed within DTAC. WNV and TB guidance documents developed and later approved by Board and made available to members on OPTN website. Spring-Summer 2013: Communication continues between DTAC and the Living Donor Committee regarding related policy questions, with LD Committee developing public comment proposal to remove specific disease requirements in policy in favor of broader language requiring development of protocol to evaluate for seasonal/geographically endemic diseases. Apr 2013: Because West Nile Virus is most prevalent in late summer/early fall, the DTAC plans to complete this document for consideration at the June 2013 Board meeting. The remaining documents are planned for Board review in November 2013. June 2013: WNV guidance approved by 10 Board. July-Aug 2013: LD Committee proposal to change donor evaluation language will be held until Spring 2104. Guidance delayed to follow proposal to the Board. Nov-Dec 2013: DTAC aggregate data studied and reviewed to analyze reports of seasonal and geographically endemic diseases reported as potential donor-derived disease transmissions. Study of this information led to creation of abstract for WTC. Jan-Feb 2014: Subcommittee appointed to develop guidance document based upon data from abstract. Reviewed focus of this group with Chair to outline that primary goal is providing guidance on suggested elements of a center protocol for evaluating potential living donors for geographic and seasonally endemic disease. Additionally, the aggregate data this group developed for the abstract could be used to specific diseases to consider in much the same way that the WNV and TB papers were laid out. Mar 5, 2014: First subcommittee call was held. April 2014: Subcommittee reconvened to review early draft template for this document and assume writing responsibilities. May 19, 2014: Group's third conference call to review draft to date and discuss finalization of the document. July 2014: Conference call will be scheduled to review latest draft and begin editing document for presentation to full committee during August meeting.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

Three separate guidance documents will be developed.

Other Solution

A guidance document was seen as the best means for conveying this information and allowing for it to be archived for easy retrieval. Adding policy language could be problematic as endemic areas could change, especially for West Nile Virus. Guidance can be updated more easily without the need for public comment.

Modifications to How New Donor Information Received Post-Transplant is Reported to Recipient Centers

Sponsoring Committee

Ad Hoc Disease Transmission Advisory

Public Comment: 2015-March

Board Date: 2015-November

Status: Evidence Gathering

Problem Statement

DTAC and DEQ case reviews have highlighted a number of instances where communication delays or failures for new donor information learned post transplant led to potential transplant recipient morbidity or mortality. This project seeks to improve communication regarding new information critical to recipient care, enhance recipient safety, and help to prevent or quickly react to potential donor-derived disease transmission. The current patient safety contact requirement must also be considered, as it is not functioning as smoothly in some institutions as others, and has presented challenges in communicating important information in some cases. After several calls with a Joint DTAC-OPO effort to build consensus on a plan to address these concerns, a determination was made in January 2014 to use an FMEA to map out the process used for OPOs receiving post-transplant information and the pathway for communicating this information to transplant centers. The FMEA process will highlight potential failure points throughout the process and provide evidence for policy development meant to enhance patient safety.

Progress To Date

01/2011: The patient safety contact policy requirement was implemented in policy. This effort comes from the OPTN Strategic Plan. This part of the three pronged project was already underway (as a previously approved committee project) prior to the release of the OPTN Strategic Plan. Fall 2011: Though all members were ultimately compliant in submitting this information, concerns have been raised that it is not as efficient as the DTAC had hoped. 2/10/2012: The Joint Subcommittee convened for the first time to discuss current communication practices and potentials for delays that might negatively impact organ recipients. Aggregate DTAC data was shared regarding recipient morbidity and mortality related to communication delays. A wide variety of experiences were shared by subcommittee members, and there was very little agreement within the group regarding a path forward- policy modification versus education. 12/06/2012: The Joint Subcommittee recognized several potential failure points in communication. The first three bullets were agreed upon as relevant to this group's work: Delay or failure of lab to report final results in a timely fashion Delay or failure of OPO to collect/acknowledge lab results Delay or failure of OPO to communicate results to transplant programs Failure of transplant program to respond in a timely manner with treatment or prophylaxis as necessary. Basic requirements agreed upon by the group include: Daily follow up on outstanding final results Share new information within 24 hours of receipt Confirmation from transplant center for receipt of information documented in donor record, not necessarily voice to voice but a confirmation. Members felt that OPOs and transplant centers should be allowed to develop their own internal policies or procedures for meeting minimum policy requirements in this area. A recommendation was made to pursue guidance in this area, but concern remained that this may not fully address patient safety concerns effectively. The Joint Subcommittee determined that it could not move forward with policy modifications without surveying the transplant community. The experiences shared within this small group were so varied that the group was not comfortable making decisions based upon their individual experiences alone. 2/15/2013: The joint DTAC-OPO Subcommittee considered developing a survey for all OPOs and transplant centers to better understand current practice for collecting final culture results and other new donor information received post-transplant, and to determine the perceived effectiveness of the patient safety contact policy requirement as currently implemented. Data from this survey will be used to formulate any necessary modifications to current policy for reporting new donor information effectively and efficiently to the "right" person at a transplant center. There was discussion to require voice-to-voice communication of new information and using the OPO Donor Console in DonorNet to ascertain a contact point at the center in lieu of requiring a patient safety contact. Survey data will help determine if this is the direction that should be pursued by the Joint Subcommittee. The POC is not supportive of surveying members. The Joint Subcommittee will continue other opportunities for language modification or

education as an alternative. The Joint Subcommittee met by teleconference to review draft survey questions to be directed to both transplant centers and OPOs. These survey questions will have to be approved by UNOS' internal survey committee before release. 3/2013: The POC did not approve DTAC's project to include a survey, noting survey fatigue within the transplant community. 9/23/13: The DTAC returned to the POC with a request to complete a survey of OPOs and transplant centers. The DTAC and OPO Committees believe that the following feedback is important for this project to be successful: member likes and concerns related to the current policy requirement for using the patient safety contact to communicate this information. This effort was approved by the POC and Executive Committee, but the DTAC's attention is currently focused solely on the PHS Guideline review project due to project size and critical timeline. 2/4/14: UNOS leadership recommended use of an FMEA (Failure Mode and Effects Analysis) to clearly map out the various steps for OPOs to receive new donor information and then communicate it to transplant recipient centers according to OPTN policy. The FMEA will provide an evidence-based approach to recognizing potential points where human error could interfere with successful communication. The standing joint subcommittee was re-appointed to include personnel who specifically carry out these functions. This will be beneficial when working through the FMEA. Feb-March 2014: Staff reviewed FMEA used for previous committee projects while working to set up a consultation with FMEA facilitator. 3/5/14: DTAC staff met with Dr. Feldman from VCU. He facilitate the FMEA used to develop policy related to ABO verification and is very interested in helping with this project as well. The FMEA will be completed by the end of September 2014, which will miss the fall public comment deadline, but allow this project to move forward for public comment in Spring 2015. 3/11/14: Initial process map and related current policy requirements were sent to Dr. Feldman for review as he develops a contract and project timeline for this work. 4/15/14: Contract with Dr. Feldman finalized. Will review updated timeline with DTAC leadership and discuss moving previously scheduled September 2014 DTAC meeting to August to coincide with half day face-to-face for FMEA joint subcommittee. Project still in line with planned timeline to complete FMEA no later than Sept 30. 5/1/14: DTAC leadership met with Dr. Feldman to review timeline and expected outcomes of the FMEA process. A draft agenda will be developed for introductory call this month. 5/16/14: Joint Subcommittee met for the first time, to learn more about the FMEA process and begin outlining a process map. 5/30/14: Joint Subcommittee reconvened to review and finalize process map. The group continued its work with the development of potential failure modes related to each step on the process map. 6/27/14: Joint Subcommittee to finalize the failure modes and begin recording the effects of potential failure modes and scoring the severity, likelihood, and detectability of each in an effort to eventually rank the critical nature of these potential failures. 7/11/14: Conference call scheduled 7/18/14: Conference call scheduled 7/25/14: Conference call scheduled (tentative due to World Transplant Congress) 8/1/14: Conference call scheduled 8/8/14: Conference call scheduled 8/13/14: in person meeting in Chicago scheduled

Possible Solutions

Policy Solution

The joint DTAC-OPO Subcommittee will employ an FMEA to better understand current practice for collecting final culture results and other new donor information received post-transplant, and to determine the perceived effectiveness of the patient safety contact policy requirement as currently implemented. Data from this study will be used to formulate any necessary modifications to current policy for reporting new donor information effectively and efficiently to the "right" person at a transplant center. The Subcommittee anticipates both modifications to existing policy and new policy language to cover these concerns. There may be opportunity for additional guidance or education to accommodate the policy changes to provide further assistance to members.

IT Solution

n/a

Instructional Solution

Webinar or other instructional module may be beneficial to the community regarding this topic. This is still under discussion by the committee at this time.

Other Solution

Educational efforts including webinars or guidance documents may also be employed either prior or in addition to policy modifications to raise awareness within the transplant community.

What to do when serologies affecting match run appearance are updated

Sponsoring Committee

Ad Hoc Disease Transmission Advisory

Public Comment:	2015-March
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

There is currently no requirement in policy to regenerate a match run if there is a change in donor infectious disease screening results would impact a candidate's appearance on the match run. This currently applies to four serology results used to screen potential recipients on or off of a match run. They include: Hepatitis B (HBV) Hepatitis C (HCV) HTLV (if donor screening was completed) CMV (pertinent only for the intestine match run, though several members noted that this was no longer clinically relevant) As a result, the joint subcommittee was made aware of centers receiving organ offers from positive donors when their recipients should have been screened from the match run. While no harm has come to recipients to date, this group supports policy to prevent potential harm and enhance patient safety in this area.

Progress To Date

Winter 2012-Spring 2013: The Joint Subcommittee has met twice to discuss this issue (late 2012, early 2013), and requested data on the frequency of allocation without final results or with results changed to positive. The Joint Subcommittee will then draft modifications to prevent potential allocation of organs without an updated match run. May-June 2013: The Committee has data to review regarding the frequency of allocation without final results or with results changed to positive and will then plan to draft modifications to prevent potential allocation of organs without an updated match run. Several attempts were made to bring this group together in early 2013, but all failed. This group is delayed in reviewing data and developing a final proposal due to inability to bring all parties together for a conference call. Release of the PHS Guideline led to the DTAC setting this project aside for a time. April 2014: Original joint subcommittee members will be asked to review data and draft language developed for the joint subcommittee based upon their discussions will be written into the new plain language format and shared with original joint subcommittee members before going back to the DTAC for consideration. A fall 2014 public comment is planned. May 2014: Internal meeting to review draft language now rewritten in plain language format planned. June 2014: Ongoing edits to draft language in preparation for joint subcommittee review July 2014: Conference call tentatively scheduled for week of July 14 to review draft language with joint subcommittee before taking it to full DTAC for review and vote. July 15, 2014: Joint subcommittee call held today. Group is still not in unanimous agreement on how to move forward with policy language in cases where a liver is accepted pending serologies. Generating a new match run may ultimately show new recipients who are a higher priority than the intended recipient. The group is torn about what to do in these cases. At least one more conference call will be needed. Participant availability is limited due to upcoming NATCO and WTC meetings, so language will not be ready by internal deadline for fall public comment. Date was updated to reflect spring public comment, still going to the Board in June in the new calendar.

Possible Solutions

Policy Solution

Change policy to require a new match run be generated when new positive HBV, HCV, or HTLV results are learned for all organs or if CMV results are positive for intestine donors. A guidance document may also be necessary to address these situations, especially if additional potential recipients were to appear on the new match run. This would involve explaining why recipients were bypassed.

IT Solution

A pop up on the match run to remind OPOs to re-run if final HBV, HCV, HTLV, or CMV (for intestine only) serologies come back positive has been proposed within the group.

Instructional Solution

Newsletter article to alert members and provide rationale and enhancements to patient safety that are related to this change.

Other Solution

The committee discussed an education only approach here, but due to patient safety ramifications it seems that policy language is the most appropriate path forward.

Define "Exhausting the Match Run"

Sponsoring Committee

Ad Hoc International Relations

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Policy currently states that "Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the Organ Export Verification Form to the OPTN Contractor prior to exporting deceased donor organs." OPOs and Transplant Hospitals have commented that the policy is unclear with regard to the level of effort required for national placement before OPOs may offer organs to foreign entities for transplant. In a previous proposal to revise this section of policy, the IRC and Ethics Committees made non-substantive changes to the export policy language. The changes were not acceptable to Region 10, AOPO, or the OPTN OPO Committee because it did not concretely define that it means for an OPO to exhaust a match run before pursuing exportation of organs outside of the U.S. A joint subcommittee of the IRC, Ethics, OPO, and Transplant Administrator Committees is charged with studying the issue to propose a solution(s) to identify the specific circumstances which must be present to indicate that allocation cannot be completed in the US and organs can be offered outside of the US.

Progress To Date

The committee will resume work on this effort, reviewing earlier modifications to Policy 3.2.1.4 (Prohibition of Organ Offers to Non-Members). The Joint Subcommittee convened on 2/3/2014 to discuss the issue. The subcommittee focused its attention on policy-related solutions, including determining some array of time where in the match sequence placement efforts would be futile. It was noted that this may vary depending on organ type. The group also discussed determining when to initiate a back-up system of offers, while the subcommittee attempts policy development efforts to address the issue. The subcommittee determined a need to review additional data to help inform their path forward. Some of the questions raised by the committee included: at what point on the match, are organs rarely, if ever, accepted by a U.S. transplant program for those organs that were exported, how far down the match were offers documented. The question was developed as a formal data request by the subcommittee. The subcommittee will reconvene to review the data and discuss options once the data request is fulfilled.

Possible Solutions

Policy Solution

Following review of the data and joint subcommittee discussion, early draft language from the inception of this project will be reviewed by the joint subcommittee for a proposed policy revision. A potential policy solution could include a requirement to make X number of offers on the match run or follow through to some minimum point on the match run based on certain factors (to be determined based on investigation and review of the evidence) before offering the organ outside of the US.

IT Solution

n/a

Instructional Solution

This proposal will require policy modifications. All member institutions will be impacted. This proposal will be monitored for instructional purposes. An instructional program will be needed prior to the implementation of policy modifications.

Other Solution

n/a

Review Deceased Donor Import Policy

Sponsoring Committee

Ad Hoc International Relations; Ethics

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

The issue was raised regarding the placement process for offers of organs recovered outside of the US. OPTN Policy states that an OPTN Member (Host OPO) is responsible for allocating deceased donor organs. However, it is also in policy and in current practice that the OPTN has the responsibility for facilitating placement of deceased donor organs recovered outside of the US without a formal agreement (Policy 17.2.B.). This is not specified in either NOTA or the Final Rule. There are a few formal agreements in existence where an OPO will use a foreign country as their local recovery area; however, foreign agencies without an agreement sometimes contact the OPTN Contractor to allocate organs. In such cases, the OPTN Contractor currently offers the organ nationally, using the hospital closest to the offering foreign agency as the "donor hospital." The OPTN Contractor uses a national version of the match run to complete this task. The match run generated in these instances is modified from what an OPO would see if it were to offer the organ. The current process is very time consuming on the part of the Organ Center (2-3 hours of work before placement efforts can begin) and annually only yields a few placements that result in successful transplants. However, these organs can be important additions to the donor pool, potentially allowing a US patient to be transplanted. Current policy language does not specify this national allocation algorithm currently used by OPTN Organ Center Staff. The committee is studying the issue to determine: If the current OPTN practice regarding offers of organs recovered outside of the US is allowed under the Final Rule/NOTA? Is the Organ Center or the OPO the most appropriate body to facilitate placement of these organs?

Progress To Date

2/10/2014: Joint subcommittee convened to discuss. The joint subcommittee was challenged with determining its appropriate focus to identify the problem statement. Potential directions discussed included: Examination of ways to improve the ad hoc exchanges using a Canadian-style model that may eventually lead to established formal organ exchange agreements, lessening the burden on the Organ Center. Examination of ways to improve the safety and efficiency of organ imports under the current process. As the work of the subcommittee evolves, this will determine whether the change model will be a policy revision or guideline. Examination of the role and function of the OPTN vs OPO in foreign organ offer placements without a formal agreement.

Possible Solutions

Policy Solution

Based on committee and internal OPTN discussion, the following outlines the most likely solutions for the committee to pursue: Formal determination of the role/function of the OPTN and OPO in foreign organ offer (without a formal agreement) and resulting policy modifications to improve the consistency, efficiency, and safety of foreign organ imports. Examination of ways to improve the safety and efficiency of organ imports under the existing process only.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Ethical Considerations of Imminent Death Donation

Sponsoring Committee

Ethics

Public Comment:	N/A
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

Imminent Death Donation (IDD) offers an avenue for increased donation of organs but there are ethical considerations, logistical, and policy issues in the transplant community that need to be overcome.

Progress To Date

Briefly discussed at April 2013 Committee Meeting - Dr. Morrissey participated and presented by web conference. April 2013 - Ethics Committee Chair presented this topic to the Living Donor Committee by web conference. October, 2013 - The Chair of the Living Donor Committee participated in the Ethics Committee discussion of this topic by web conference. The Living Donor Committee Chair provided a list of concerns the Committee had identified regarding IDD. March 2014 - The Ethics Committee discussed IDD during its full Committee meeting and heard presentation Drs. Morrissey and Sheiner. The Ethics Committee approved the following resolution: The Ethics Committee recognizes that IDD as an emerging donation practice may be ethical under certain circumstances but feels that significant ethical, clinical and practical concerns must be addressed before policy development. The Committee therefore recommends that a joint subcommittee be formed including the Kidney, OPO, Living Donation, and Ethics Committee to further explore IDD and address concerns. The Ethics Committee is considering the development of the position paper addressing IDD. In the process of forming a workgroup with members of the OPO, Living Donor and Operations and Safety Committees to begin this work. June 2014- The Executive Committee of the Board approved this project. July 2014 - Have list of representatives for a workgroup from OPO, Ops and Safety and the LD Committee. Alexandra Glazier will Chair the workgroup. A first meeting is scheduled for August 14, 2014.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

This proposal could require policy modifications and system changes. Imminent Death Donation offers an avenue for increased donation of organs. There are ethical considerations and logistical issues in the transplant community that need to be overcome. If ultimately approved, the transplant community could want instruction on implementing protocols for this type of donation.

Other Solution

The Ethics Committee will prepare a position statement on this topic. This statement, if approved by the Board, can be used by other Committees in the formulation of policy proposals related to IDD.

Review Existing White Papers for Accuracy and Relevancy

Sponsoring Committee

Ethics

Public Comment: N/A

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

The OPTN web site provides access to 10 white papers developed by the Ethics Committee. These oldest white paper on the site was approved in 6/93, and it is unclear when these resources have been reviewed for accuracy and relevancy.

Progress To Date

The Ethics Committee met on 3/10/14 and discussed this potential new project and discussed possible approaches for reviewing the proposals.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

This proposal is operational in nature and is not anticipated to effect existing policy. Once these resources are updated they should be promoted for use within the transplant community.

Other Solution

The review of these papers will also consider adding a sunset date to these resources so they will be reviewed on a regular basis.

Addressing HLA Typing Errors

Sponsoring Committee

Histocompatibility

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

HLA typing errors can have serious patient safety implications, including graft loss, accelerated rejection, or death in some cases. There are also instances where an HLA typing error results in system inefficiencies (increased cold ischemia time, discards, and possible missed transplant opportunities for other candidates). The OPTN does not currently have a policy or system for timely reporting or oversight of HLA typing errors. (discrepancies are flagged on the donor and recipient histocompatibility forms completed after transplant, but there is currently no timely mechanism for detecting errors used for the match run).

Progress To Date

This project is ongoing as part of the overall histocompatibility policy rewrite project that was approved by the POC & Executive Committee in 2012. Since the Committee is still discussing solutions for these problems and the larger rewrite has already been completed and will be presented to the BOD in June 2014, this part of the proposal is now considered a separate, ongoing project. In 2012, the committee formed the Discrepant HLA Typing Subcommittee to review data and provide conclusions and recommendations for policy changes. In August 2013, the subcommittee presented the initial findings of HLA discrepancies: Match Run vs Donor Histocompatibility Form: 1% of deceased donors 90% are technical errors Match Run vs Recipient Histocompatibility Form: 4.5% of donors 43% are transcription errors Donor Histocompatibility Form vs Recipient Histocompatibility Form: 2.3% of donors 43% are transcription errors The Committee has discussed a number of solutions to address HLA typing errors (see proposed solutions section below). The Discrepant HLA Typing subcommittee is going to finalize recommendations for the full committee in summer/fall 2014.

Possible Solutions

Policy Solution

There is overwhelming support from the Committee for changes in policy that would provide accountability for laboratories that make HLA typing errors--especially for the MPSC to take disciplinary action in cases of serious errors. The subcommittee recently discussed defining a serious HLA typing error as a wrong antigen assignment where the HLA type reported for a deceased donor was used for the match run and the result was that an organ was allocated incorrectly, either to a recipient who was transplanted with an incompatible organ or where the organ had to be re-allocated upon realization of the error. In these cases, the Committee has discussed requiring the laboratory to report the error to the transplant program(s) and/or OPO(s) who received incorrect HLA typing and to UNOS through the patient safety portal. UNOS staff (DEQ) and the MPSC would then review the change. These new requirements will likely be included in the rewrite of the Histocompatibility Bylaws. Other possible solutions have been identified to prevent HLA typing errors from occurring prior to allocation or to detect them prior to transplant: Require second person confirmation for reporting HLA The committee was generally in favor of this solution and suggested clarifying that one of the reviewers must be from the histocompatibility laboratory. This was intended to address reporting errors that may be occurring because the person entering the data (OPO or transplant hospital staff) is not an HLA expert. One committee member also pointed out that ASHI currently requires a second party verification on analysis of DNA based typing, but recognized that not all OPTN laboratories are accredited by ASHI. The committee requested that the subcommittee draft a new requirement to be presented to the full committee. Require recipient laboratories to re-type deceased donors The committee is somewhat divided on this idea. Data show less than 50% of deceased kidney, kidney-pancreas, and pancreas donors are re-typed by the recipient laboratory and, therefore, it is difficult to have a complete understanding of the scope of HLA typing discrepancies.

Several members suggested that the Committee review data on the frequency of retyping by laboratory in order to understand how many laboratories retype deceased donors currently. Several members of the Committee are in favor of this new requirement, arguing that donor re-typing is essential in order to confirm that the organ received is the one accepted for the intended recipient. Others added this requirement is important due to increased use of virtual crossmatching. However, some members have expressed concern that this would possibly be an expensive burden on laboratories and suggest instead that the committee focused on finding solutions that prevent HLA typing errors prior to allocation. Several members commented that the majority of typing errors are clerical or due to interpretation issues and requiring recipient laboratories to retype will not solve this problem. The committee members concluded that there is some interest in this solution but still quite a few concerns and, therefore, requested that the subcommittee continue to discuss this solution. Require third party 'tie breaker' laboratory to resolve the error. Several committee members had concerns about this solution, particularly with which party would ultimately be responsible for covering the cost of the retyping. One member suggested that the laboratory determined to be in error should pay for the cost. Others suggested that UNOS pay for the third party typing, predicting that this would be a small number of cases. Another member suggested that, in certain circumstances, the laboratories involved in the discrepancy could submit their typing results to the third party laboratory in order to resolve discrepancies resulting from differences in interpretation of the results (not a typing error).

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

CPRA Manuscript

Sponsoring Committee

Histocompatibility

Public Comment: N/A

Board Date: N/A

Status Evidence Gathering

Problem Statement

The goal of this manuscript is to describe the changes in CPRA distribution that have occurred since the CPRA replaced PRA for kidney allocation (October 1, 2009). This manuscript is the final step in CPRA monitoring done by the Histocompatibility Committee and will require minimal additional data analyses. It will be based on the data reports already put together for the committee.

Progress To Date

Almost all data for this manuscript have been gathered as part of the monitoring CPRA implementation project.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Enhancing Prioritization for DR Matching in Deceased Kidney Donor Allocation

Sponsoring Committee

Histocompatibility

Public Comment: 2016-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

Under OPTN policy, potential recipients are given 2 additional points during deceased kidney donor allocation if there are no mismatches between a donor and recipient's HLA-DR. One additional point is given if there is one DR mismatch and no additional points are given if there are two or more DR mismatches. The Committee has reviewed data that show a strong link between HLA-DR matching and long-term graft survival in kidney transplantation. However, the percentage of zero-DR mismatch transplants remains relatively low.

Progress To Date

This project was originally larger in scope and included an assessment of whether prioritization points should also be given for HLA-DQB matching. The subcommittee met in September and November 2013 to review data on long term graft survival of deceased donor kidney transplants by DR and DQB mismatch. The data show the following: 22% of transplants were zero DR mismatches and 23% were zero DQB mismatches 60% of transplants had the same level of DR and DQB mismatch. This percentage was higher for 0 and 1 DR mismatch levels compared to 2 DR mismatch (67% and 67% vs. 48%). Recipients with lower levels of DR mismatch had significantly higher survival within 8 and 12 years post transplant. Recipients with a zero DQB mismatch transplant had significantly better survival within 8 and 12 years compared to those with higher DQB mismatch levels. Survival rates for 1 and 2 DQB mismatch level transplants were similar. Better survival rates for zero DQB mismatch transplant recipients was probably affected by a high percentage of zero DQB mismatch transplants that also had a zero DR mismatch level (67%). Within each DR mismatch level, survival was similar by DQB mismatch level. 0/0 DR/DQB recipients had significantly better survival rates comparing to all other groups with DR mismatch levels higher than 0. Differences between 0/0 vs. 0/1 and 0/0 vs. 0/2 groups were not significant. The subcommittee reached the following conclusions: Recipients with lower levels of DR MM had significantly better long term (within 8 and 12 years) survival There is some indication that better DQB matching leads to better long term survival (0MM vs. 1MM and 0MM vs. 2MM) Survival doesn't seem to be improved by DQB matching in addition to DR matching or better DQB matching within the same level of ABDR mismatch The subcommittee is now focused on the question of whether more prioritization points are needed for transplants with lower levels of DR mismatches. The subcommittee will soon review simulation modeling performed during the development of the new kidney allocation system (KAS) to determine whether the changes implemented at the end of 2014 are likely to increase or decrease the number of zero-DR mismatch

Possible Solutions

Policy Solution

The Committee has discussed increasing the number of points and prioritization given to kidney candidates for lower levels of DR mismatches (beyond just points for zero or one mismatch as the policy is currently).

IT Solution

Programming prioritization for higher levels of DR mismatches in the kidney allocation system.

Instructional Solution

n/a

Other Solution

n/a

Expanding HLA Typing Requirements

Sponsoring Committee

Histocompatibility

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

The Committee has identified several problems with the current HLA typing requirements: There are inconsistencies in the HLA typing requirements for deceased donors across organ types, although this information is critical for the transplant team in making decisions about donor acceptance or post-transplant monitoring for all organ types. Recent research suggests that antibodies to HLA-DQA and HLA-DPB are frequently observed in sensitized transplant candidates and, if donors with the relevant types are not avoided, these antibodies can contribute to adverse graft outcomes. However, there are no fields in DonorNet to report HLA-DQA or HLA-DPB in deceased donors, and these types are not required to be reported. There are currently no HLA typing requirements for deceased pancreas islet donors or islet candidates. Several publications have implicated HLA alloantibodies in rejection of islets and HLA typing could be crucial for evaluating risk from pre-transplant and de novo HLA alloantibodies. Currently, OPTN policy requires histocompatibility laboratories to perform molecular typing on deceased kidney, kidney-pancreas, and pancreas donors only, despite the much superior typing accuracy and advantages this can bring to all transplant candidates.

Progress To Date

This proposal is a piece of the comprehensive histocompatibility policy rewrite proposal that the POC and Executive Committee approved as a project in 2013. 12/2/13: The Committee voted to distribute this for public comment in Spring 2014. The POC and Executive Committee approved this project for public comment in Spring 2014. 07/22/14: Public comment has been favorable thus far, with overwhelming support from individuals, regions, and committees. The Committee presented an update on this proposal during the June 2014 Board meeting. The update primarily focused on showing new DPB and DQA data.

Possible Solutions

Policy Solution

If the laboratory is performing typing on any deceased donor (whether required or simply requested and on all organ types), the lab must perform molecular typing. Laboratories must report results for HLA-DQA and HLA-DPB on deceased kidney, kidney-pancreas, and pancreas donors. Laboratories must perform molecular typing and report results for DR51, DR52, and DR53 for deceased thoracic donors if the candidate's physician requests HLA information prior to acceptance. Laboratories performing typing on deceased pancreas islet donors must perform molecular typing and report results for A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DPB, DQA, and DQB. Laboratories must perform molecular typing on pancreas islet candidates and report results for A, B, Bw4, Bw6, and DR (Change: make these fields required on Waitlist).

IT Solution

Add fields for HLA-DQA and HLA-DPB in DonorNet (if not already approved in June 2014 request to the Board) and make them required for offers for kidney, kidney-pancreas, and pancreas. Make HLA fields for A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DPB, DQA, and DQB required for pancreas islet offers. Make HLA fields for A, B, Bw4, Bw6, and DR required for pancreas islet candidates on Waitlist.

Instructional Solution

There will likely to be system training on this proposal if it is approved.

Other Solution

n/a

Histocompatibility Bylaws Rewrite: Phase 2

Sponsoring Committee

Histocompatibility

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

Many of the OPTN Bylaws governing histocompatibility laboratories are out of date, vague, or more appropriately monitored by the histocompatibility accrediting agencies. This second phase will attempt to clean up sections pertaining to the education and experience required for approval as key laboratory personnel, along with performance indicators for testing performed and results reported to the OPTN.

Progress To Date

The Committee met throughout 2013 to begin work on the second phase of the histocompatibility bylaws rewrite. The Committee has drafted new language for the following sections: C.3.A: There are two education pathways for approval for OPTN histocompatibility laboratory directors--M.D./D.O. or PhD. For each the committee has drafted new language that would specify the education, experience, and licensing requirements. The Committee is also hoping to specify that foreign equivalent education and experience is permissible (there is currently no pathway for foreign equivalent education and experience in the Bylaws for laboratory directors). C.3.B: The Committee is proposing to simplify requirements for the technical supervisor by only requiring that this individual meet the requirements in CLIA regulations. C.3.C: The Committee is proposing to simplify requirements for the general supervisor by only requiring that this individual meet the requirements in CLIA regulations. C.3.D: The Committee is proposing to simplify requirements for the clinical consultant by only requiring that this individual meet the requirements in CLIA regulations. C.3.E: The Committee is proposing to eliminate references to the histocompatibility technologist. The Bylaws do not have requirements for this group of personnel. C.6.A: The Committee is proposing a number of changes in the section that lists criteria for mandatory performance reviews of histocompatibility laboratories. The Committee is proposing to create a new criteria around HLA typing errors that result in an incompatible transplant or instances where an organ has to be reallocated because of an HLA typing error. C.7.A-J (excluding I): the Committee is proposing to delete a number of these sections that are out of date or are more appropriately monitored by ASHI or CAP. The next scheduled call is April 29, 2014. The Bylaws Rewrite Subcommittee undertook an extensive review of the Bylaws during teleconferences held on May 16, and May 29, 2014. The Bylaws Rewrite Subcommittee reported their recommendations to the Committee on the June 3, 2014 Histocompatibility Committee teleconference call. On June 13, 2014, Committee leadership presented the Bylaws Rewrite Phase II proposal to the ASHI Board of Directors for recommendations in anticipation of a final Committee vote on June 26, 2014. On June 26, 2014, the Committee met to review feedback from ASHI's Board on the Bylaws Rewrite Phase II proposal. The Committee agreed with a recommendation from ASHI to allow for 4 years pre-doctoral experience as one of the many qualifiers for a laboratory director. The Committee voted unanimously to approve the amended proposal to release for fall 2014 public comment.

Possible Solutions

Policy Solution

See above progress to date section to reference the list of solutions the Committee has been discussing.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Histocompatibility Testing Guidance Document

Sponsoring Committee

Histocompatibility

Public Comment:	N/A
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

Many of the current OPTN policies governing histocompatibility testing are vague and more appropriate as guidance. The Committee identified 28 sections of policy in this category as part of the comprehensive histocompatibility rewrite project.

Progress To Date

This project is being marked as an ongoing project because it was previously approved as part of the histocompatibility policy rewrite project. This project is being proposed in order to fully resolve all of the 'parking lot' items identified in the OPTN policy rewrite project. The Committee has identified 28 sections of the policy that would be appropriate for a guidance document: History of Allosensitization Detection of Alloantibody: Creating an Antibody History Periodic Sample Collection Crossmatching Strategies Documenting allosensitization Assays to identify alloantibody (antibody screening or crossmatching) Recommended elements for crossmatching strategies. Typing Assignment Reagent Validation HLA Typing Nucleic Acid Analysis Typing by Sequence Based Typing (SBT) Antibody Screening Techniques Sera Panel and Target Selection Antibody Screening Techniques Samples Cytotoxicity Methods Controls Target Cells Complement Chimerism Analysis Analysis and Reports Nucleic Acid Analysis Flow Cytometry Enzyme Linked Immuno Sorbent Assay (ELISA) Solid Phase Multi-channel Arrays

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

Once the guidance document is approved, the community will need to be informed that it exists and the benefit to using it to guide clinical practice at OPTN laboratories.

Other Solution

Those sections of policy that do not contain member requirements, but may nonetheless be useful to members, will be converted into guidance documents and other educational materials.

Changes to KAS: CPRA and priority for patient's undergoing desensitization

Sponsoring Committee

Histocompatibility; Kidney

Public Comment:	2015-September
Board Date:	2016-June
Status	Evidence Gathering

Problem Statement

Under the kidney allocation system, highly sensitized kidney candidates who undergo desensitization lose allocation points associated with their CPRA score, reducing their opportunity for kidney offers.

Progress To Date

1/22/14: A workgroup comprised of members of the Histocompatibility, Kidney, and Minority Affairs Committees held an introductory call. The members agreed on the problem statement. The members also discussed barriers to getting data on how many patients would benefit from a policy change. The workgroup decided that the most effective step for moving forwarding is to conduct a survey of kidney transplant programs to learn whether more programs would utilize desensitization for highly sensitized candidates if these candidates could keep the prioritization associated with their CPRA score for a period of time. The workgroup also requested data to determine whether there is a level of sensitization (indicated by CPRA score) where patients would most benefit from desensitization, whether this change would benefit minority populations in particular, and whether the modeling previously provided on the new Kidney Allocation System (KAS) showed increased or decreased access for certain categories of sensitized patients that the workgroup should focus on.

Possible Solutions

Policy Solution

The KAS Desensitization Workgroup is currently discussing the following solutions: Creating a variance to the new KAS that will allow sensitized kidney candidates who are undergoing or have undergone pre-transplant desensitization within a certain time period (still TBD) to retain the CPRA score assigned pre-desensitization for a certain period of time (one year has been discussed). Kidney transplant programs or regions could apply for this variance. A national kidney allocation policy change that will allow sensitized kidney candidates who are undergoing or have undergone pre-transplant desensitization within a certain time period (still TBD) to retain the CPRA score assigned pre-desensitization for a certain period of time (one year has been discussed). Kidney transplant programs or regions could apply for this variance.

IT Solution

The proposed solution would require a variance or changes to the new kidney allocation system.

Instructional Solution

n/a

Other Solution

n/a

Addressing Geographic Disparities in Deceased Donor Kidney Allocation

Sponsoring Committee

Kidney

Public Comment: 2016-March

Board Date: 2016-November

Status Evidence Gathering

Problem Statement

The OPTN Final Rule states that a candidate's place of residence shall not restrict his/her access to transplantation. However, there is huge variation to access to transplantation amongst the OPTN donation service areas (DSAs).

Progress To Date

This project is building upon the efforts of the Liver Committee and the Policy Oversight Committee. In 2012, the Board directed the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013. The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represent patient outcome. The Kidney Committee made some preliminary determinations in 2013 and the POC presented these metrics to the Board at its June 2013 meeting. The Kidney Committee has been working to refine their metric since that time. February/March 2014: The Geographic Disparities Subcommittee met in February and March 2014 to review the following data by DSA: Offer rate per 100 active patient years Transplant rate per 100 active patient years Supply/demand ratio (where supply reflects quality of organs and demand represents waiting list population) Median time to transplant (competing risks method) In addition, offers, transplants, and "supply" were calculated for three different donor groups: All deceased kidney donors Deceased kidney donors with KDPI greater than or equal to 85% Deceased donors with KDPI greater than or equal to 85% and non-DCD The subcommittee also reviewed data to determine whether to use an incident (newly listed) or prevalent (entire list) patient population to define the denominators of the offer rate, transplant rate, and supply to demand ratios. As a result of assessing changes to both the numerators and denominators of these ratios, the subcommittee considered six different types of transplant rates, six different types of offer rates, and twelve different types of supply v. demand metrics, for a total of 24 different metrics. In addition, the Committee reviewed an analysis of the median (and 25th percentile) times to transplant by DSA. In addition to quantifying the degree of DSA-to-DSA variability by each of the 24 ratios, the correlation between each metric and all others was evaluated to determine which choices –e.g., changes to numerator vs. changes to denominator—would have a larger effect on the optimization modeling to be used for determining new districts. If two metrics are highly correlated, the decision of which one to use would have relatively little impact compared to the choice between two metrics that are weakly correlated or uncorrelated. The following key findings were reported: There is huge variation in access to kidneys across DSAs for all of these metrics. The results suggest that case-mix differences (e.g., DSA's with higher proportion of sensitized candidates) may explain at least some of this variability, in particular in offer and transplant rates. It is often impossible to estimate median times to transplant due to fewer than 50% of candidates being transplanted in certain DSAs as well as competing risks (e.g., removal from the waiting list for death and other reasons). Excluding lower quality kidney donors had very little impact on the rank ordering of DSA's by either offer rates, transplant rates, or supply-to-demand ratios. The following decisions are expected to have a much larger impact on the development of new districts based on mathematical optimization: Including all or only recently listed patients (incident v. prevalent waiting list) Including all or only active patients The class of metric to use (offer rates, transplant rates vs. supply-to-demand ratios) After reviewing these data, the subcommittee decided to recommend including all kidney donors (no exclusion of DCD or high KDPI donors) for supply-to-demand, offer rates, and transplant rates. The subcommittee also recommended including only active patients. The subcommittee reported that they are leaning toward an incident-based metric to avoid overcompensating for historical, accumulated disparities, but the members agree that any such time period should be made prior to announcement of any new redistricting proposal to avoid gaming. There was some concern that, depending on how recent the incident population is, it may take a substantial amount of time to resolve inequities. The subcommittee members expressed concerns that using a transplant rate metric does not account for variation in center acceptance practices. Similarly, there is a concern that, no matter the metric

selected, it will likely be difficult to account for behavioral changes and OPO performance. April 7, 2014: The subcommittee presented an overview of this data and the few decisions reached thus far at the in-person meeting. Generally, the Committee agreed with the subcommittee recommendations. Dr. Friedewald suggested that the subcommittee look at data on a couple of large, multi-center DSAs to help decrease influence of listing practices and hold supply steady. Dr. Turgeon (along with other committee members) also cautioned that as the subcommittee moves along in its work, it will need to look at whether decreasing geographic disparities increases other types of disparities (for example, racial disparities). It was also suggested that the subcommittee look at dialysis exposure as a metric. There was some concern that dialysis exposure at the time of transplant would be limited, in that it doesn't capture disparity for those patients who have been on dialysis for a lengthy time that do not get transplanted. Members also expressed a preference to reassess geographic disparity after implementation of the new Kidney Allocation System (KAS), which is expected to have at least some effects on the geographic distribution of kidneys. The Committee also expressed the importance of having some flexibility in periodically reassessing any metric selected and recalibrating geographic boundaries if necessary.

Possible Solutions

Policy Solution

This proposal will follow a similar path to the liver redistricting project. 1) This proposal would eliminate the use of 'local' in the kidney allocation algorithms. 2) Once the Committee settles upon a measurement of fairness, new regions will be drawn to reduce geographical disparities between these regions. This proposal would require new definitions for these districts. These districts will be built from OPO boundaries. The new definitions would similar reference these OPO boundaries to construct the new districts. Because pancreas allocation is intertwined with kidney allocation, modeling for the new districts will need to consider both organs.

IT Solution

This proposal will follow a similar path to the liver redistricting project. 1) This proposal would eliminate the use of 'local' in the kidney allocation algorithms. 2) Once the Committee settles upon a measurement of fairness, new regions will be drawn to reduce geographical disparities between these regions. This proposal would require new definitions for these districts. These districts will be built from OPO boundaries. The new definitions would similar reference these OPO boundaries to construct the new districts. Unlike liver, this will not require any changes to review board operations.

Instructional Solution

n/a

Other Solution

n/a

Develop national standard for marking organ laterality

Sponsoring Committee

Kidney

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

A total of 13 cases of switched kidney laterality have been self-reported to UNOS since 2012. In three of these cases, one or both of the switched kidneys was not transplanted due (at least in part) to the laterality switch. Because there is no uniformity or policy on whether this kind of marking is done or what kind of marking is done, this can create confusion particularly for receiving transplant centers across different DSAs. This issue was the third highest ranked failure mode identified during the Failure Modes Effects and Criticality Analysis (FMECA) conducted by Northwestern University on the current deceased donor organ procurement process as part of the Electronic Tracking and Transport Project.

Progress To Date

Recommendation received from Ad Hoc Organ Tracking Committee in June 2013. This proposal was originally approved by the POC/Executive Committee for the Operations and Safety Committee. This project was transferred to the Kidney Committee in early 2014. July 2014: The 'Marking Kidney Laterality Workgroup' (comprised of Kidney Transplantation and Operations and Safety Committee members) will hold an introductory conference call on 08/05/14.

Possible Solutions

Policy Solution

Many OPOs have developed practices to mark correct kidney laterality such as using a clip or stitch on one of the kidneys. These practices were started to prevent switched lateralities that may occur during the process of moving an organ from the back table to the organ container. Depending on the scope of the problem and the will of the transplant community, this could be developed as a policy or issued as a guidance document.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Simultaneous Liver Kidney Allocation

Sponsoring Committee

Kidney

Public Comment:	2015-September
Board Date:	2016-June
Status	Evidence Gathering

Problem Statement

Kidneys are sometimes allocated to liver candidates who regain their kidney function following a solitary liver transplant. If a liver candidate does not accept a kidney at the time a liver is offered and then does NOT regain native renal function following a solitary liver transplant, that individual may wait for years on dialysis for a kidney. So the allocation system provides only disincentives for forgoing a kidney offer. This leads to fewer transplants for kidney-alone candidates and may disproportionately affect pediatric candidates who are often drawing from the same donor pool as liver-kidney candidates.

Progress To Date

The Committee understands that for those individuals who receive a solitary liver and then do not regain their native renal function, the kidney allocation system offers little recourse and so the practice of SLK transplant continues to grow. In 2009, the Committee released a joint proposal with the Liver Committee to create clinical criteria to identify which candidates should receive an SLK transplant and create a safety net for those candidates who did not meet the clinical criteria and later continued to experience renal failure after a solitary liver transplant. That proposal, while well received during the public comment process, was ultimately shelved because of programming complexities that could not be overcome at the time. With the implementation of a new kidney allocation system expected by the end of 2014, the complexities that prohibited implementation of this proposal previously are no longer an obstacle. The Committee agreed that it is necessary to pursue this potential policy change at this time as multi-organ transplant affects all candidates on the kidney transplantation list. Pediatric kidney transplantation candidates are disproportionately affected because SLK donors are more likely to be younger than 35. Further, the Policy Oversight Committee has tasked the organ specific committees with developing (a) a safety net to protect patients who have undergone an isolated liver transplant then subsequently have renal dysfunction that does not recover and (b) medical criteria to determine eligibility for receiving a kidney allograft at the time of liver transplantation.

January, 2014: The Kidney committee leadership and staff submitted an abstract to WTC with SLK data to receive feedback on the need for possible new allocation rules for SLK transplants. April 7, 2014: the Committee reviewed results from the following data requested at their August 2013 in-person meeting:

1. Clinical information for SLK recipients at time of transplant for transplants performed since 2005, including percent on dialysis, time on dialysis (<6 months, 6+ months), creatinine values, primary diagnoses for kidney and liver transplants, donor quality (KDPI), MELD by creatinine, and sensitization level (PRA/CPRA).
2. Number of listings for kidney after liver transplant for each year since 2005 by Region and DSA; and distribution of time between the liver and subsequent kidney listings including the proportion with kidney listings within certain time period (e.g., within one and three years) after the liver transplants, stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nephrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.
3. Number of kidney transplants after liver transplants each year since 2005 by Region and DSA; and distribution of time between the liver and subsequent kidney transplant including the proportion with kidney transplants within certain time period (e.g., one and three years) after the liver transplants, separately for deceased and living donor transplants, and stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nephrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.
4. 25th and 50th percentiles of times to transplant for registrations waiting for kidney after liver and for registrations waiting for kidney with no previous liver transplants by blood type. Explore the feasibility of computing percentiles of time to transplant for each blood type, by Region and DSA (feasibility may be limited by sample size). The results were summarized as follows:
 - Among 3,431 SLK recipients during 1/1/05-6/30/13, 510 (15%) did not receive pre-transplant dialysis and had a serum creatinine of $><2.5$ mg/dl at transplant, which would suggest that some of these patients may not have needed a kidney. Of the 510 SLK recipients with no pre-transplant dialysis and a serum creatinine of $><2.5$ mg/dl, 237 (46%) received a KDPI >

<35% kidney, which suggests that kidneys utilized in SLK transplants also tended to have a lower KDPI scores. Since pediatric kidney candidates are prioritized to receive kidneys from donors with age><35 (KDPI>

Possible Solutions

Policy Solution

The policy proposal may include: a safety net to protect patients who have undergone an isolated liver transplant then subsequently have renal dysfunction that does not recover and medical criteria to determine eligibility for receiving a kidney allograft at the time of liver transplantation.

IT Solution

This proposal may require changes to the kidney allocation system.

Instructional Solution

n/a

Other Solution

n/a

Allowing Deceased Donor Chains in the OPTN KPD Pilot Program

Sponsoring Committee

Kidney Paired Donation

Public Comment:	2015-September
Board Date:	2016-June
Status	On Hold

Problem Statement

Chains have the greatest potential for increasing the number of transplants in the OPTN KPDPP. In November 2012 the BOD approved open non-directed donor chains in an effort to increase the number of KPD transplants. Although we are awaiting programming to implement open chains, we will be limited in the number of transplants performed by the number of non-directed donors entered in KPD. Deceased donor chains, combined with open chains and bridge donors, have a great potential to increase KPD transplants.

Progress To Date

The idea generated from an email from (then) UNOS President John Roberts. Kidney committee leadership has had initial discussions regarding this topic. HRSA has requested a review of NOTA and the Final Rule in regards to this project. August, 2013: Kidney Committee leadership and UNOS staff met to discuss how to move this topic forward. The group is communicating through email about the potential controversies that may arise from discussing this topic more broadly. Once the group works through these barriers they plan to bring the discussion before the KPD Work Group and the Kidney Committee. Currently there seems to be support for using a variance model to test starting a chain with a deceased donor. The group does not expect this topic to move overly quickly. September, 2013: UNOS leadership requested that the Kidney Committee leadership consult with HRSA before moving forward on the project and before formally engaging the KPD Work Group. March, 2014: This topic was briefly discussed with HRSA. A more in-depth memo is being drafted for review and a call will be scheduled for a discussion. April, 2014: Staff is drafting the memo to send to HRSA. May 2014 Update: Staff circulated memo to internal KPD team.

Possible Solutions

Policy Solution

Before deceased donor organs could be used in a KPD exchange, several topics would need to be addressed, including: Which deceased donor kidneys could be shared with a KPD program; Which KPD candidates are eligible to receive a deceased donor kidney as part of a KPD exchange; Would this be restricted to the OPTN KPD pilot program only or made available to all KPD programs? One possible solution could be that an available deceased donor kidney and donor information would be entered into the KPD program to begin a chain. The living donor in the first pair of the chain would need to meet criteria to be a bridge donor and would be entered as a bridge donor in the next match run after his/her candidate was transplanted with the deceased donor kidney. The details of donor criteria and match process would need to be discussed with the transplant community. The KPD Workgroup will work with the kidney transplant community to understand potential concerns and barriers to deceased donor chains and develop a model that will be acceptable to the majority of the community. The Workgroup will look to gather input from the community in a variety of ways, similar to KAS, before developing a final proposal. Once the proposal has been developed and approved by the Kidney Transplantation Committee it will go out for the usual public comment cycle.

IT Solution

Merging the deceased donor match run with the KPD match run.

Instructional Solution

n/a

Other Solution

n/a

KPD - All Other Guidelines to Policy

Sponsoring Committee

Kidney Paired Donation

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

If the OPTN/UNOS Board makes the OPTN KPD permanent in June 2014, then the remaining KPD operational guidelines will need to be converted into policy. Many of those guidelines are individual projects (KPD histo guidelines to policy, KPD informed consent guidelines to policy, etc.) but this proposal serves as a catch-all for the remaining guidelines that will need to be converted. For the Donor Pre-Select section - the KPDPP Operational Guidelines require candidates with CPRA >90% to indicate pre-selections for potential donors. If they don't enter the pre-selection, then the potential donor will be automatically pre-refused, and the candidate will not have the opportunity to match with the donor in future match runs unless the transplant program enters a pre-acceptance in the KPD system. This section needs to be converted to policy 13. KPD Contact Responsibilities must also be included in this proposal.

Progress To Date

Staff are evaluating the current guidelines and policies to determine what actions must be taken on each topic. March, 2014: Staff presented recommendations for which guidelines should be converted to policy to the KPD Workgroup on 2/19. A workgroup is forming to tackle this project with more frequent meetings. April, 2014: Staff is outlining the issues to be addressed that aren't caught by the other projects. May 12 2014: Donor pre-select, the logistics guidelines, KPD contact responsibilities - all should be packaged together in one proposal. The proposal needs to be ready for Kidney Committee vote on June 30. July, 2014: The Kidney Committee review of this proposal was postponed. The Kidney Committee will review this proposal during its August 4, 2014 meeting.

Possible Solutions

Policy Solution

These operational guidelines will move into Policy 13 (Kidney Paired Donation). The concepts have already been developed and vetted as guidelines but will need to be written in the same format as other OPTN policies.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

KPD Histocompatibility Guidelines to Policy

Sponsoring Committee

Kidney Paired Donation

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

The OPTN KPD program still has a relatively low match success rate. While matches can fail for a variety of reasons, a number of failed matches in the OPTN KPD program are due to histocompatibility issues (unexpected positive crossmatches and unacceptable antigens). Upon review of the failed matches due to histocompatibility issues, the KPD workgroup recommends new policies to improve efficiency in the KPD program.

Progress To Date

03/14/14: Released for public comment 06/13/14: Public comment period closed. Overview of public comment: 45 total individual comments 41-support 2-oppose 2-had no opinion One individual who opposed the proposal requested amendments to remove the requirement for molecular typing to be performed on candidates. The other individual was unclear whether the KPD system would be programmed to allow programs to report the review/approval of unacceptable antigens. Without this programming, the commenter believes it will be very burdensome to KPD programs. All 11 regions supported the proposal. Region 1 commented that the requirement for recipient laboratory to retype the donor was too burdensome. Region 4 recommended that HLA-DPA typing be added on KPD donors and longer timeframes be allowed between antibody screenings for non-sensitized candidates (180 days was suggested). AST issued the following comment: We find the proposal strong and well written. The AST supports the proposal. We believe the changes will increase efficiency in arranging compatible matches and facilitate transplants for candidates enrolled in KPD. ASTS issued the following comment: ASTS supports this proposal regarding requirements for histocompatibility testing on donors and recipients in the OPTN KPD program. ASTS is pleased that the committee considered recommendations from the March 29-30, 2012 KPD consensus conference in Herndon, VA in formulating this policy proposal. 07/14/14: The Kidney Committee will discuss and vote on whether to recommend this proposal at the September 29 in-person meeting. 07/15/14: The committee staff met to discuss and review business requirements for the proposal.

Possible Solutions

Policy Solution

The proposal includes the changes below. Please note that some of the changes are already required through programming or in the OPTN KPD pilot program guidelines required to participate in the program, and this change simply moves those requirements into OPTN policy. Items that are new are highlighted in the below list. HLA typing is required for donors and candidates in order to be eligible for match runs in the OPTN KPD Program The potential donor's hospital is responsible for all HLA reporting requirements on the donor The transplant hospital registering the candidate in the OPTN KPD program is responsible for all HLA reporting requirements on the candidate HLA typing for donors and candidates must be performed using molecular methods (New) The following HLA types are required to be reported for potential donors in the OPTN KPD program: HLA-A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, DPB (New) The following types are required to be reported for candidates in the OPTN KPD program: HLA-A, B, Bw4, Bw6, and DR (New) If a candidate has unacceptable antigens listed for the following, these additional types are required to be reported for the candidate: HLA-C, DR51, DR52, DR53, DQA, DQB, and DPB (New) The candidate's transplant hospital is responsible for retyping a matched donor to confirm the donor's HLA information (New) The candidate's transplant hospital is responsible for all antibody screening requirements on the candidate Candidates must be screened for antibodies using a method at least as sensitive as the crossmatch method and using a solid phase assay (New) Antibody screenings are required 1) every 90 days, 2) when a potentially sensitizing event occurs, 3) if the candidate has been reactivated after being inactive for more than 90

days, and 4) if an unacceptable positive crossmatch occurs that precludes transplantation (New) The candidate's physician or surgeon (or designee) and the affiliated histocompatibility laboratory director (or designee) must review and confirm the unacceptable antigens reported for a candidate (New) The candidate's transplant hospital is responsible for performing a physical crossmatch before the donor's nephrectomy is scheduled and a final crossmatch prior to the transplant. The candidate's transplant hospital must report crossmatch results to the matched donor's hospital and the OPTN Contractor (New) If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the candidate's transplant hospital must inactivate the candidate before the next scheduled match run, review and update the candidate's unacceptable antigens, and report a reason for the unacceptable crossmatch to the OPTN Contractor within 7 days of the date that the crossmatch results were received by the candidate's transplant hospital. (New)

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

KPD Informed Consent Guidelines to Policy

Sponsoring Committee

Kidney Paired Donation

Public Comment: 2014-September

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

In November 2012 the Board approved a number of KPD guidelines for inclusion in OPTN policy, but some sections were withheld for further development. The KPD informed consent guidelines for candidates and for donors were one of those sections.

Progress To Date

In November 2012 the Board approved a number of KPD guidelines for inclusion in OPTN policy, but some sections were withheld for further development. The KPD informed consent guidelines for candidates and for donors were one of those sections. Since that time, the Joint Societies appointed a Joint Societies Workgroup (JSWG). They workgroup met throughout 2013 and sent their recommendation to the Joint Societies' parent organizations. The recommendation is largely similar to the one that was released for public comment in 2012 with one notable exception. The 2012 public comment proposal focused on participants in the OPTN KPD program whereas the 2013 JSWG proposal is expanded to all KPD programs. Feb, 2014: Two of the three societies have responded in support of the proposal. The workgroup is still waiting on ASTS response. If ASTS responds in time, and if the KPD Workgroup approves the JSWG proposal, the plan is to send the informed consent proposal for public comment in the fall of 2014. If the Kidney Committee does not agree to expand the proposal to all KPD programs (and limits it to participants in the OPTN program), then they could send this to the Board for consideration this summer. April 2014: All three societies have expressed their approval and the Work Group is meeting on April 25, 2014 to review the JSWG proposal and see whether any additional changes need to be made. May 2014: On April 25, 2014 the KPD Workgroup met and approved the JSWG proposal as written. The informed consent proposal will now take two paths: 1) the Kidney Committee will vote on whether to put the informed consent proposal into guidelines immediately (by voting on June 30th); and 2) the Kidney Committee will vote whether to send this proposal out for public comment in Fall 2014 on June 30. July 2014: The June 30 Kidney Committee teleconference was postponed. The Kidney Committee will now meet on August 4 to determine whether the informed consent proposal should be sent out for public comment during the Fall 2014 cycle, and whether it should be put into Operational Guidelines in the meantime.

Possible Solutions

Policy Solution

Policy sections 13.3 and 13.4 were reserved for this proposal during the plain language rewrite. Most of these requirements already exist in the OPTN KPD Operational Guidelines.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Membership Requirements for KPD Centers

Sponsoring Committee

Kidney Paired Donation

Public Comment:	2015-March
Board Date:	2015-November
Status	Evidence Gathering

Problem Statement

For a candidate to be eligible to participate in KPD, they need to meet the following conditions: Be at an approved kidney transplant program Be at an approved living donor kidney recovery program Be entered in KPD by the center who registered the candidate in Waitlist The MPSC no longer requires all programs that do living donor transplants to be living donor recovery centers. The primary example of this is children's hospitals when the living donor nephrectomy is performed at a nearby adult hospital. Under the current rules for KPD, children registered at children's hospitals that are not living donor recovery hospitals would be precluded from participating in the OPTN KPD program. The KPD Work Group would like to rectify the problem of disenfranchising children from the program.

Progress To Date

UNOS staff has identified a programming solution for this problem. However, because the topic impacts multiple committees, the work group did not want to proceed without broader input. March, 2014: Staff met to discuss the policy and programming implications. The consensus seemed to be that KPD should be treated similar to other organ types in the membership system. That way other aspects of eligibility, such as providing info about key personnel, can also be maintained within that system. One question is how the new KPD system can interact with the membership system. Staff met again and discussed solutions that would be similar to living donor membership solutions. These would only require minor bylaws change. The KPD, Living Donor, and Membership committee staff will work together to draft proposed language before presenting it to the respective committees. Everyone agreed this should not be controversial for any of the committees or the community. April, 2014: No updates

Possible Solutions

Policy Solution

Remove the requirement that a KPD program be a living donor recovery hospital if that program will not be performing living donor recoveries.

IT Solution

Remove the programming requirement that a KPD program must be a living donor recovery hospital.

Instructional Solution

n/a

Other Solution

n/a

Revising KPD Priority Points

Sponsoring Committee

Kidney Paired Donation

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

Many centers do not enter their easy to match pairs in KPD programs but instead reserve these pairs for KPD exchanges within their own centers. When there are mostly hard to match pairs in the pair pool, it is more difficult to find matches because the easy to match pairs are needed to match with the difficult to match pairs. The system currently consists of 63% of candidates with a CPRA of greater than or equal to 80%. When so many candidates have high levels of unacceptable antigens, it is difficult to find matches because 63% of candidates have difficulty finding a donor. Additionally, centers wish to act in the best interest of their patients so they will likely choose to do an internal exchange over a match with a sensitized candidate at another center. Currently which pairs are offered KPD matches is partly based on a set of Prioritization Points.

Progress To Date

The KPD Optimization Algorithm and Design Subcommittee (DOAS) has met several times to review data. Subcommittee members are now conducting simulations to determine the optimal prioritization scheme. August, 2013: All but one data request has been reported to the DOAS. They are communicating over email about how to translate these data into actionable improvements in the program. September, 2013: Staff will be meeting with subcommittee members to make sure they have access to the data they need for the simulations. Policy staff will be discussing different methods for structuring the prioritization section of policy including whether it can delineate principles of prioritization rather than specific point values. Feb, 2014 : Tuomas and Itai will present update to KPD Workgroup on 2/19. In the meantime, the prioritization points section of KPD Policy 13 already went out for public comment in March 2012 and should be moved into Policy this summer. This will allow the workgroup to continue work on the optimization. Some workgroup members are concerned about the rigidity of the policy structure and want to discuss other options. Specifically, they wish to write a matching algorithm that adapts to a changing donor pool. Staff discussed ways to construct such a system in our policies while still maintaining transparency and a collaborative policy development process. March, 2014: UNOS is working with Tuomas to determine the IT aspects of the prioritization algorithms. In the meantime he is continuing his studies and he and Itai will present their statuses to the KPD DOAS workgroup on March 7 and to the KPD Workgroup on March 25.

Possible Solutions

Policy Solution

The KPD Workgroup is reviewing the prioritization point system to determine if changing the system will increase transplant program participation and increase the number of KPD transplants performed. The workgroup is discussing solutions to increase the number of transplant programs who participate in KPD; increase the number of pairs and NDD's enrolled; increasing the number of matches found and offered; and decreasing the number of match declines/increasing the number of match acceptances. The group will look at program data and results of the KPD Barriers survey to determine optimal ways to improve the program.

IT Solution

Solutions may result in a change in the optimization algorithm or edge finder or edge weighter.

Instructional Solution

n/a

Other Solution

The KPD workgroup is reviewing the prioritization point system to determine if changing the system will increase transplant program participation and increase the number of KPD transplants performed. The KPD Workgroup is exploring the following: what will increase transplant program participation what will increase the number of pairs and non-directed donors enrolled in the KPDPP what will increase the number of matches found and offered what will increase the number of matches accepted/decrease the number of declines.

Cap HCC Exception Score @ 34**Sponsoring Committee**

Liver and Intestines

Public Comment: 2014-March

Board Date: 2014-November

Status Post Public Comment

Problem Statement

Candidates with a MELD/PELD score exception for HCC receive high priority on the liver waiting list, especially as their exception scores may increase automatically every three months. Increasingly, there are candidates with multiple HCC exception extensions who are now receiving regional offers under the “Share 35 Regional” policy implemented in June 2013. These candidates are likely to have a much lower risk of disease progression or dropout (i.e., removal from the waiting list for death or being too sick) than candidates with calculated MELD/PELD scores of 35 and higher.

Progress To Date

This is one of three projects that were originally sent to the POC as one project. (Changes to HCC Exception Allocation Policy) The projects were split into three because the Committee devised three different solutions to the problem and will send them to public comment separately. Feb. 2014: This proposal was released for Spring 2014 Public Comment. June 2014: Public comment was reviewed by the Committee on the 06/13 Call. The Committee has opted to reconvene the HCC Subcommittee to review and address the feedback more in depth. The proposal will likely be forwarded to the Board in Nov. without substantial change.

Possible Solutions**Policy Solution**

This proposal would cap the HCC exception score at 34.

IT Solution

This proposal would cap the HCC exception score at 34.

Instructional Solution

n/a

Other Solution

n/a

Changes to Criteria for Auto Approval

Sponsoring Committee

Liver and Intestines

Public Comment:	TBD
Board Date:	TBD
Status	On Hold

Problem Statement

There is a subset of candidates that have a very low risk of disease progression or dropout who are receiving HCC exception points. Data from Region 5 indicate that candidates with one small lesion (2-3cm), with a complete response to the first ablative treatment, and an AFP after treatment that was less than 20ng/mL, had a cumulative risk of dropout from tumor progression or death of 1.3% at 1 year and 1.6% at 2 years. Based on these data, it is possible to identify a group of candidates who do not need an exception (unless there is tumor recurrence). Cases that fit these criteria could still be reviewed by the RRB but would not be eligible for automatic HCC points. Candidates meeting these criteria may account 20% those with HCC exceptions. These candidates may need some higher level of priority if the tumor ultimately advances rapidly, in which case the center could appeal to the RRB.

Progress To Date

This is one of three projects that were originally sent to the POC as one project. (Changes to HCC Exception Allocation Policy) The projects were split into three because the Committee devised three different solutions to the problem and will send them to public comment separately. February 2014: The Committee decided not to send this for public comment in the Spring 2014 cycle until additional data can be gathered on HCC recurrence. The Committee may want to work on this project as time is available as HCC exceptions continue to be problematic.

Possible Solutions

Policy Solution

For candidates who meet the criteria in Policy 9.3.G, the HCC exception application is automatically approved in UNet without Regional Review Board (RRB) review. An analysis of one large center's data identified a subset of candidates that meet these criteria who have a very low risk of disease progression or dropout from the waiting list due to death or becoming untransplantable, and may not need a transplant for years, if ever. Under this proposal, these candidates would not be eligible for an automatic HCC exception until their tumors recur or exhibit more aggressive behavior. This proposal would also require that all candidates undergo locoregional therapy (LRT) prior to the application in order to be eligible for an automatic exception. Centers would still be able to petition the RRB if there are additional considerations that may warrant MELD exception for HCC or for candidates for whom locoregional treatment is contraindicated

IT Solution

This requires reprogramming the HCC exception application in UNet.

Instructional Solution

n/a

Other Solution

n/a

Delay HCC Exception Score Assignment

Sponsoring Committee

Liver and Intestines

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

Patients with a standard MELD exception for hepatocellular carcinoma (HCC) have lower rates of waitlist dropout and higher transplant rates than those without an exception. As approximately 25% of the deceased donor transplants are done in patients who had an HCC exception (2011 data), the priority assigned to HCC exceptions affects access to transplant for non-HCC patients.

Progress To Date

One proposed solution to address the disparities in drop-out rates between patients with HCC exceptions and those without is to delay the score assignment by 6-months. LSAM modeling has shown that this would equalize the transplant and drop-out rates for those with and without HCC exceptions. This analysis was presented at the 2013 American Transplant Congress (ATC) in 2013. February 2014: This proposal was released for Spring 2014 Public Comment. July 2014: Public comment was reviewed by the Committee on the 06/13 Call. The Committee has opted to reconvene the HCC Subcommittee to review and address the feedback more in depth, however the proposal will likely be forwarded to the Board in Nov. without substantial change.

Possible Solutions

Policy Solution

This proposal would delay the HCC exception score assignment for 6 months, as presented at ATC this in 2013.

IT Solution

This would require reprogramming the automated MELD HCC exception application form.

Instructional Solution

If significant changes are proposed, this may require a webinar prior to implementation.

Other Solution

n/a

Develop materials to educate RRB members / promote consistent review of exceptions

Sponsoring Committee

Liver and Intestines

Public Comment: N/A

Board Date: N/A

Status Evidence Gathering

Problem Statement

Regional Review Board members have varying degrees of understanding about their duties, liver allocation policies, and the RRB process. Several RRBs meet during regional meetings or via conference calls to discuss specific cases as well as to determine a common approach to case review, while other RRBs rarely if ever convene as a group. Members of the Liver Committee have requested more formal training of all Regional Review Board members to promote consistent review across the country.

Progress To Date

The Committee has reviewed the prior and current RRB Operational Guidelines. Committee members have identified differences in the way RRBs operate (e.g., some have regular calls, some meet at Regional meetings, some have specific criteria for exceptions or timeframes for voting, etc.). The Committee has also identified the need to better educate incoming/new RRB members about MELD/PELD exception policies. February 2014: The educational materials are being piloted in Region 5. They be rolled out to other regions following the pilot.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

Several Committee members have suggested that UNOS provide on-line learning modules that RRB members would have to successfully complete prior to serving their terms.

Other Solution

Educational materials could cover topics related to RRB member requirements and qualifications, review board operations, and how to handle common exception requests.

Liver Distribution Redesign Modeling (Redistricting of Regions)

Sponsoring Committee

Liver and Intestines

Public Comment:	2015-March
Board Date:	2015-November
Status	Evidence Gathering

Problem Statement

The current DSA and regional boundaries used for distribution of livers were not designed to optimize equitable organ distribution. There are observed differences between the mean MELD score at transplant and the rates of transplant and death by DSA and region. This does not comply with the Final Rule's requirement to distribute organs over as broad a geographic area as feasible. The SRTR is developing maps of potential new distribution units designed to decrease disparities while not increasing organ transport times beyond what the community considers acceptable.

Progress To Date

The Committee determined the top metrics they believe should be used to reduce geographic inequities in liver allocation, and have provided feedback on the number of geographic units or regions that would be desirable, and the maximum organ transport times that would be acceptable. The SRTR demonstrated several redistricted maps during the March 13, 2013 and September 23, 2013 meetings. Preliminary information will be provided in the Fall 2013 Regional meeting presentations. The Committee is continuing to review data and maps in anticipation of public comment in 2014. February 2014: The Committee will review additional map/data at its 4/1/2014 meeting. It is possible that the Committee may select a map (or more than one map) at this meeting. A Steering Committee has been formed in order to develop a timeline for ultimate submission for Public Comment and to the Board. July 2014: The concept document was released on 06/16/14. Responses to the accompanying questionnaire were gathered through 07/11/2014. 694 responses were received. The public forum is confirmed for 09/16/2014 at the Hilton Rosemont, in Rosemont, Illinois. The Steering Committee plans to enlist key speakers and panel discussion focused on the topics that were identified in questionnaire responses.

Possible Solutions

Policy Solution

1) This proposal would eliminate the use of 'local' in the liver allocation algorithms. 2) This proposal would require new definitions for liver districts. These districts are being built from OPO boundaries. The new definitions would similar reference these OPO boundaries to construct the new districts. This will also impact the operations of the regional review boards since the number of regions/districts would change. The Committee has a separate project for work on a national liver review board proposal. This would not change the definition of regions used for committee representation.

IT Solution

This would require reprogramming of the match to remove 'local' liver offers and utilize new region/district definitions.

Instructional Solution

n/a

Other Solution

n/a

National Liver Review Board

Sponsoring Committee

Liver and Intestines

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

The Board asked that the Committee develop a plan for a national review board, to be presented at the June 2014 meeting. Board members felt that the current RRB system does not promote consistent reviews/MELD scores across the US.

Progress To Date

The Committee has reviewed the 2004 proposal for a national review board and has developed an updated plan that will be submitted for Board consideration in June 2014. The Committee presented the updated idea/concept and sought input from the Board at the June meeting on the further development of a NRB. The Board approved and urged the Committee to move forward at this time rather than waiting for Redesigning Liver Distribution.

Possible Solutions

Policy Solution

Most review board operations are in the review board guidelines. The policies contain multiple references to the liver "regional review board." Similar to the Lung Review Board, these references would need to be updated to the "Liver Review Board."

IT Solution

This would require the current RRB case management system to be revamped to accommodate a pool of reviewers who would be randomized for reviews, and to ensure some pediatric expertise on those cases.

Instructional Solution

n/a

Other Solution

Most review board operations are in the review board guidelines. These guidelines will need to be updated with new review board compositions.

Ongoing review of MELD/PELD Exceptions

Sponsoring Committee

Liver and Intestines

Public Comment: N/A

Board Date: 2014-November

Status Pending Board Approval

Problem Statement

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. Many of the exceptions submitted do not fall under one of the diagnoses listed in policy, but are submitted as 'Other, specify.' The submission, review, and approval of these exceptions varies across regions. The MELD Enhancements and Exceptions subcommittee has reviewed a recent list of these 'other specify' diagnoses, and plans to develop criteria for several diagnoses. These may begin as guidelines before being proposed for new policy. The Committee has decided to focus on MELD exceptions while the PELD Allocation Working group reviews the PELD score.

Progress To Date

The MELD Exceptions and Enhancements Subcommittee is planning to develop exception guidelines and templates for several often-requested exceptions, for diagnoses such as neuroendocrine tumors, polycystic liver disease, and primary sclerosing cholangitis. February 2014: The MELD Exceptions Subcommittee will propose exception guidelines for 3 additional diagnoses: neuroendocrine tumors, primary sclerosing cholangitis, and polycystic liver disease. These 3 diagnoses account for a large percentage of the non-standard exception requests. June 23, 2014: The Board approved the guidance document on its consent agenda (36-2-0). The second guidance document will be forwarded to the Board for consideration at the November 2014 meeting.

Possible Solutions

Policy Solution

This could affect several sections of Policy.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

The Committee may develop standard guidelines that could lead to standardized policy. This path has been taken before and seems to foster community buy-in and awareness. For example, the Committee developed basic guidelines for the exception that are now in policy, and then further refined those with the MESSAGE conference and paper, and ultimately swept those into policy.

Criteria for Intestine Surgeons and Physicians

Sponsoring Committee

Liver and Intestines; Membership & Professional Standards

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

There are no criteria for intestine transplant surgeons and physicians as for other organs. The intent is to set minimum levels of experience for intestine surgeons and physicians, which should serve to better protect patients.

Progress To Date

The Liver Committee submitted a proposal for public comment in August 2006, but it was not well-supported, and the proposal was withdrawn before Board consideration. The main concerns expressed were that a large number of well-qualified programs and smaller volume programs would not be able to meet these requirements, and that that no training program in the country would have met the requirements as written. The Committee was aware that the American Society of Transplant Surgeons (ASTS) was developing its own criteria for intestinal program accreditation that would set levels for volume and experience, so it agreed to postpone this effort until after the ASTS made its recommendations. The ASTS finalized its criteria for fellowship training programs in September 2008. A Subcommittee of the LTC made initial recommendations applying the bylaws for liver transplant surgeons and physicians with the ASTS volume numbers (10 transplants per year) as a starting point. These were presented to the MPSC in November 2009, and objections were expressed similar to ones regarding the prior proposal. In December 2012, the Subcommittee presented recommendations to the MPSC, and once again concerns about the volume requirements were expressed because the number of intestine transplant surgeries has been declining since 2007. Concerns about how the bylaw would be implemented also resurfaced. In order to facilitate better cross-committee communication, a joint Liver-MPSC subcommittee was created in the fall of 2013. This joint subcommittee made several modifications to the proposal to address the concerns that have been expressed. In December 2013, the MPSC reviewed the most recent recommendations, and indicated that the proposal as amended addressed their concerns and was ready for public comment. This proposal was released for public comment in March 2013. 07/14/2014: The Committee reviewed public comment received and opted to reconvene the Intestinal Subcommittee on 07/16/14 with the intent of addressing this feedback more in depth and recommend any post public comment changes to the proposal in response.

Possible Solutions

Policy Solution

The Committee will propose minimum levels of experience for intestine surgeons and physicians. The structure of these bylaws will be similar to the other organs but the specific content and threshold levels will be specific to intestine transplants.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Revisiting the PELD Score

Sponsoring Committee

Liver and Intestines; Pediatric

Public Comment:	TBD
Board Date:	TBD
Status	On Hold

Problem Statement

The PELD score has not been modified since it was implemented in 2002. A high proportion of pediatric patients are transplanted in Status 1 or with a PELD exception, which indicates that a review is needed. This was highlighted in a paper by Salvalaggio, et al (AJT2005; 5: 1868–1874): "In summary, we have assessed whether the PELD system has improved liver allocation for children as measured by changes in recipient status and regional variation in listing practices. Overall waiting list mortality has not changed and there appears to have been no impact on post-transplant survival. The use of exceptions is common and may have an adverse effect on the intended functions of PELD. Regional variation suggests that PELD has not resulted in standardization of liver allocation in pediatric liver transplantation. Adjustments in the PELD score and elaboration of standard criteria for granting points by exception may improve the outcomes for children awaiting liver transplantation."

Progress To Date

The PELD Allocation Working group was convened in February 2013 and has met via teleconference. The group has requested several analyses, some of which have already been requested and reviewed by the Pediatric Committee, and are thus already available. The PELD Working Group met on July 9. The call resulted in two data requests: For a recent cohort, provide a tabulation of PELD score exception requests by diagnosis Using LSAM, model the impact of increasing priority for 1) local PELD candidates and 2) local and Regional PELD candidates. October, 2013: The LSAM analysis was tabled by the Liver Committee so that modeling efforts could focus on the potential impact of new allocation regions with different geographical boundaries on pediatric liver allocation. The requested PELD analysis was tabled because modifying the geographical boundaries of allocation regions is anticipated to have a greater impact on pediatric liver allocation. Each Committee did review the PELD score exception requests tabulation at their respective in-person meetings. Due to the heterogeneity and sudden progression of disease in pediatric liver candidates it may be necessary to establish a certain threshold of priority for all pediatric liver patients, similar to how pediatric kidney candidates are prioritized. The next PELD working group call will be used to discuss this further. November, 2013: The PELD Working Group met via teleconference on November 20. The Working Group feels as though it has effectively "revisited" the PELD Score and the conclusion is that tweaking the PELD calculation is unlikely to address the concerns regarding allocation by exception scores. The group believes that this remains an important issue and intends to request the mandate from the sponsoring committee be broadened to allow examination of pediatric liver allocation policy in more general terms. The PELD Working Group is preparing an update to the Liver Committee to receive at its April 1 meeting. Due to redistricting, this project is temporarily on hold.

Possible Solutions

Policy Solution

The workgroup looked at several possible solutions. One proposed approach is to re-estimate the PELD coefficients using a more recent cohort of pediatric patients. Alternatively, the PELD working group has discussed setting minimum diagnostic criteria for pediatric candidates together with possible allocation changes, such that pediatric candidates are listed when they need a transplant, and can get also transplanted quickly so that they do not have developmental issues that may persist throughout their lifetimes. The group also considered some parameters for often-requested exceptions, such as those for biliary atresia. The Working Group feels as though it has effectively "revisited" the PELD Score and the conclusion is that tweaking the calculation is unlikely to address the concerns regarding allocation by exception scores. The group believes that this remains an important issue and intends to

request the mandate from the sponsoring committee be broadened to allow examination of pediatric liver allocation policy in more general terms. Other possible solutions preliminarily discussed include prioritizing pediatric liver candidates for livers from donors younger than 35 (similar to Share 35 for kidneys) and multiplying each PELD score by some set factor.

IT Solution

Changes to PELD calculation or allocation priority plus minimum criteria, would require programming.

Instructional Solution

n/a

Other Solution

n/a

Clarify Status of Domino Donors

Sponsoring Committee

Living Donor

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

There are inconsistent practices regarding whether domino donors are considered living or deceased donors. Examples include: SRTR and MPSC analysis; Tiedi help documentation; LD follow-up, LD medical evaluation; LD informed consent; and donor registration.

Progress To Date

Staff have begun research on the different policies and practices impacted by domino donors. The LD Committee is planning to provide draft policy recommendations to the Liver and Ops and Safety Committees prior to their fall 2014

Possible Solutions

Policy Solution

Policy 1.2 - Add definition for domino donor Develop policy for domino liver donation similar to Policy 6.5.F (Allocation of Domino Donor Hearts) Modify Policy 18.1 Data Submission Requirements to clarify follow-up forms not required for domino donors Modify Policy 14 (Living Donor) to exclude domino donors where appropriate.

IT Solution

Current plan would be to handle domino liver donor follow-up forms (average 10 forms per year) manually. If an automated solution is available in the future it could require programming to prevent living donor follow-up forms from being generated for domino donations. and would be a small programming project.

Instructional Solution

This proposal will require policy modifications and system changes. While there is a limited number of domino donors, there will be member impact. This proposal will be monitored for instructional purposes. A small to moderate instructional program will likely be needed prior to the implementation of policy modifications and system changes.

Other Solution

n/a

Guidance Document Addressing Abnormal Lab Results During LD Follow-up

Sponsoring Committee

Living Donor

Public Comment: N/A

Board Date: 2014-November

Status Evidence Gathering

Problem Statement

During his tenure as OPTN President, John Roberts requested that the LD Committee investigate developing a resource to address how centers should handle abnormal lab values obtained during required living donor follow-up and reporting. Dr. Roberts commented that abnormal labs results could lead to unnecessary additional medical testing. This project was not supported by the POC or Executive Committee. In 2013, Ken Andreoni supported the LD Committee developing a resource to assist primary care physicians, living donors and potentially insurances companies to better understand that an 'abnormal creatinine' after a surgical nephrectomy does not have the same predictive value as a creatinine change in someone with two native kidneys

Progress To Date

The project was approved the POC and the Executive Committee of the Board. The subcommittee has been discussing how best to proceed with this project.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

This proposal is currently being monitored for instructional purposes. This document will be of value to members and may be an excellent resource for future instructional programs.

Other Solution

Living organ donors may have persistent abnormal lab values post donation. For example, living liver donors may have persistent low platelets counts. This proposed resource would provide guidance on if additional testing should be provided or required for a living liver donor with a persistent low platelet count.

Improve Reporting of Aborted Procedures and Non Transplanted Organs

Sponsoring Committee

Living Donor

Public Comment:	2015-March
Board Date:	2015-November
Status	On Hold

Problem Statement

Current OPTN policy requires living donor recovery programs to register a living donor using the Living Donor Feedback form prior to the living donor organ recovery procedure. The Living Donor Feedback form requires the transplant program to enter a response for the question “Aborted Procedure After Donor Received Anesthesia?” before the form can be successfully submitted. Options for responding to the required question include “Yes”, “No”, and “N/A.” A message on the form instructs the user to select “N/A” as the option to complete the form before surgery and to change the response to “Yes” or “No” after surgery. However, OPTN policy does not specifically require the transplant program to update the response regarding aborted procedure on the Living Donor Feedback form post operatively. Additionally, Policy 18.5.D (Report of Non-transplanted Living Donor Organs) requires member to report whenever a living donor organ is recovered by not transplanted through the Improving Patient Safety Portal. However, current OPTN policy does not specifically require updating the Living Donor Feedback form if a living donor organ is recovered but not utilized. Consequently, if a living donor is not transplanted and the Living Donor Feedback form is not updated post operatively the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms for the living donor would not generate and the living donor could be lost to follow-up.

Progress To Date

This proposed project was approved by the POC and Executive Committee of the Board. The LDC has a related project with a policy proposal that has completed public comment (spring 2014) and is slated for Board consideration in November 2014. This project is titled Proposal to Require the Reporting of Aborted Living Donor Recovery Procedures. Under this project and proposal, living donor recovery would be required to report aborted living donor organ recovery procedure through the UNet Improving Patient Safety portal. During development of this Proposal to Require the Reporting of Aborted Living Donor Recovery Procedures, UNOS Research identified existing policy does not specifically require living donor recovery programs to revise the Living Donor Feedback form for aborted living donor recovery procedure or if a living donor organ is recovered but not transplanted. Consequently, a living donor who donated an organ that is not transplanted could be lost to follow-up. The Committee has had very preliminary discussions regarding this project and will limit work on this project until the related policy language has been considered by the Board.

Possible Solutions

Policy Solution

Propose modification of Policy 18.1 (Data Submission Requirements) to require living donor recovery hospitals to revise the Living Donor Feedback form post operatively aborted living donor recovery procedure or if a living donor organ is recovered but not transplanted

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors

Sponsoring Committee

Living Donor

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

In November 2012, the OPTN/UNOS Board approved new policies for living kidney donor consent, medical evaluation and follow-up, and now similar policies for living liver donors need to be developed. A Joint Societies Work Group (JSWG) has prepared policy recommendations for similar policies for living liver donors, which the committee will use in the development of proposed new living liver donor policies. Additionally, there are other living donors (ex. lungs) that do not currently have requirements for living donor consent.

Progress To Date

The proposal was distributed for public comment and received strong overall support.

Possible Solutions

Policy Solution

The project would create a need to modify Policy 14.3 (Informed Consent Requirements), and would be modified to have requirements that apply to all living donors, and specific requirements that apply to living kidney donor and living liver donors.

IT Solution

n/a

Instructional Solution

This proposal will require policy modifications. Requirements for all living donors as well as liver and kidney will be modified. Living liver transplant programs, as well as the other living transplant programs will be impacted. This proposal will be monitored for instructional purposes. A moderate instructional program will likely be needed prior to the implementation of the policy modifications.

Other Solution

n/a

Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors

Sponsoring Committee

Living Donor

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

In November 2012, the OPTN/UNOS Board approved new policies for living kidney donor consent, medical evaluation and follow-up, and now similar policies for living liver donors need to be developed. A Joint Societies Work Group (JSWG) has prepared policy recommendations for similar policies for living liver donors, which the committee will use in the development of proposed new living liver donor policies

Progress To Date

The Committee approved policy language for public comment and forwarded the proposal to the POC and Executive Committee for release. The proposal was released for public comment on March 14, 2014. The proposal received strong overall support during the public comment process.

Possible Solutions

Policy Solution

The project would create a need to modify Policy 12.3 (Medical Evaluation), and would be modified to have requirements that apply to all living donors, and specific requirements that apply to living kidney donor and living liver donors.

IT Solution

n/a

Instructional Solution

This proposal will require creation of new policies. All living liver transplant programs will be impacted. This proposal will be monitored for instructional purposes. A moderate instructional program will likely be needed prior to the implementation of the new policies.

Other Solution

n/a

Require Reporting of Aborted Living Donor Organ Recovery Procedures

Sponsoring Committee

Living Donor

Public Comment: 2014-March

Board Date: 2014-November

Status Post Public Comment

Problem Statement

Policy require the reporting of living donor deaths and loss of native organ function, and utilized or redirected living donor organs via the Patient Safety System. The Committee is aware of living donor kidney recovery surgeries that were aborted due to intraoperative error. These aborted surgeries were not reported because the donor did not donate their kidney so the recovery hospital did not consider it a living donor adverse event. The Living Donor Feedback form contains a question addressing "aborted procedure after donor received anesthesia" however per UNOS Membership, this data element is not tracked.

Progress To Date

The Committee approved policy language for public comment and forwarded the proposal to the POC and Executive Committee for release. The proposal was released for public comment on March 14, 2014. There was no opposition to the proposal during the public comment process.

Possible Solutions

Policy Solution

Modify existing policy to require reporting of unsuccessful living donor organ recovery procedures.

IT Solution

In November 2010, the BOD approved the proposal to require the reporting of non-utilized and redirected living donor organs. The programming aspect of this proposal is to make enhancements to the living donor adverse event reporting form in the Improving Patient Safety portal. Requirements for the enhancement have been approved and the project is currently awaiting prioritization by the POC/Executive Committee. Once the proposal to require the reporting of aborted living donor organ recovery procedures is passed by the BOD, new requirements in this regard will be added to the existing project that is currently awaiting prioritization.

Instructional Solution

This proposal would require policy modifications and system changes. While there are a limited number of aborted recovery procedures, there will be member impact. This proposal will be monitored for instructional purposes. A small to moderate instructional program will likely be needed prior to the implementation of policy modifications and system changes.

Other Solution

n/a

New Requirements for the Transport of Living Donor Organs

Sponsoring Committee

Living Donor; Operations & Safety

Public Comment:	TBD
Board Date:	TBD
Status	Evidence Gathering

Problem Statement

The Committee was 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 county may be required. The number of transported living donor organs is rapidly increasing related to the increase in kidney paired donation. Transportation delays and/or failures occur in 1% - 2% of deceased donor organ shipments coordinated by the OPTN/UNOS Organ Center, despite the fact that the Organ Center is very experienced in coordinating the transport of deceased donor organ. Thus it is possible that the failure rate for the transport of living donor organs coordinated by transplant centers with little experience in such transport will be even higher. However, for living donor organs, even a failure rate of 1% - 2% is unacceptably high; living donor organs must reach their destination. Failure involving the transport of living donor organs could have a devastating impact not only on the living donors whose organs are lost but on the viability of the KPD initiative by undermining public trust and confidence.

Progress To Date

The Living Donor Committee (the Committee) first discussed this topic in May 2010, and determined that policy had very specific requirements for organ packaging but no specific requirements for how packaged organs must be required if they leave the donor recovery center. During its April 2011 meeting, the Committee approved a set of Recommendations to Reduce Transportation Delays or Failures for Living Donor Organs. Additionally, in spring 2011 the Committee released a proposal for public comment titled Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Material. Under the updated the packaging and shipping requirements for living donor organs to mirror to the extent possible existing and more stringent policy requirements for the packaging and shipping requirements for deceased donor organs. The proposal specified which transplant center had responsibility for specific tasks related to labeling and shipping living donor organs and included the development of a new labeling system specific to living donor organs. This proposal was approved by the Board in November 2011. During its April 2012 meeting the Committee discussed a new HRSA sponsored project to investigate electronic tracking of donated organs. The Committee determined it should delay work on new requirements for the transport of living donor organ until this project concluded to avoid any duplication of effort. The Ad-Hoc Organ Tracking Committee reported its final recommendations to the OPTN/UNOS Board in June 2013. An Ad-Hoc Organ Tracking Committee representative provided an overview of this project to the Living Donor Committee in September 2013, and verified that the current project does not address and at this time is not planned to address the packaging and transport of living donor organs. In response, the Committee resumed discussion of this project during its fall 2013 meeting. For the 2013-2014 approved committee projects, this project was made a joint project for the Living Donor and the Operations and Safety Committees. In December 2013, a representative of the Committee participated on an Operations and Safety Committee meeting to provide an overview of the Committee work on this project to date. The Committee discussed forming a workgroup which could include OPO Committee representatives, and discussed developing a concept paper on this topic that could be distributed for public comment. The leadership of the Living Donor Committee discussed if this project might benefit from a FMEA, which could provide evidence of potential problems and risks for failure in the current organ transport process. The Operations and Safety Committee used a FMEA for its ABO Proposal (distributed for spring 2014 public comment) and FMEA was used in the project to investigate electronic tracking of donated organs. The Committee anticipated that components of the electronic tacking of donated organs FMEA could be utilized in the development of new requirements for the transport of living donor organs.

Possible Solutions

Policy Solution

The committee will consider where the transportation of living donors is substantively different than the transportation of deceased donor organs, whether there are any gaps in the current policies, and whether any policies need to be modified to correct these gaps.

IT Solution

n/a

Instructional Solution

This proposal has been on hold due to the ETT project. There is to be a joint workgroup with the Ops and Safety Committee. This proposal is being monitored for instructional purposes. There will likely be policy modifications that will impact living donor programs. An instructional program may be needed.

Other Solution

n/a

Approved Transplant Fellowship Training Programs

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Many of the training pathways (residency/fellowship) in the bylaws require the training to occur at a fellowship program certified by certain professional societies/boards or by the MPSC based on a set of criteria outlined in the bylaws. though the bylaws say, "the MPSC will review surgical training programs every five years or any time the program director changes," the MPSC has not traditionally "certified" training programs nor reviewed training programs to make sure they meet certain standards.

Progress To Date

Only had one meeting with work group to consider, pending further discussions with general counsel before can identify a path forward. 5/19/14- This project was included in those topics to be discussed by the Joint Societies Working Group. This group will ultimately make recommendations for the MPSC's consideration. The JSWG roster was recently finalized as of May 2014. 7/22/14 JSWG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of approved transplant fellowship training programs among other JSWG items to be discussed is TBD.

Possible Solutions

Policy Solution

Remove reference to an MPSC approved training program and require acceptable training programs to be certified by professional societies/boards only.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Composite Pre-Transplant Metrics

Sponsoring Committee

Membership & Professional Standards

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

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. Current methods focus on lack of transplants performed; based on GAO report in April 2008, this was identified to be an area for development.

Progress To Date

This project began in 2008 and has recently picked up some momentum now that the MMRF are working on the statistical analysis reproduction. There is concern that the turnover in committee members every year impacts the progress. There is the potential for implementation of this for only kidney and liver programs at first due to the SRTR having to recreate the acceptance rates models and work they are doing on the other PSR related data. The Community has been involved some, but its been a while since we've had any further discussions externally about this metric. There will be some concern about the data used by the MPSC and it's potential use by payers including CMS as well as publication of these data. The composite pre-transplant metric was adjusted in response to feedback from a 2011-2012 pilot and survey. At its December 2013 meeting, the MPSC reviewed updated data produced using the adjusted metric for liver and kidney. The MPSC decided to proceed to public comment with this metric. The Committee will review proposed bylaw language at its March 2014 meeting and expects a proposal to go out for public comment in the Fall of 2014. The proposal has been referred back to the work group to address a few concerns. The MPSC will review proposed bylaw language at a June 2014 conference call to keep the proposal on track for Fall 2014 public comment. Proposal language was approved at the June 17, 2014 MPSC conference call.

Possible Solutions

Policy Solution

If the MPSC adopts this new metric, a bylaw will need to be crafted to summarize the methods for identification of programs using the statistical analysis. Because of existing triggers for pre-transplant performance, as well as feedback (governmental to include GAO) and work beginning in 2008, this is the solution the MPSC is focused on evaluating. CuSUM, which is to be developed by the SRTR, may be a tool used by the members, but will not be an adequate alternative to CPM.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Consider multi-organ procurement requirement for primary surgeon criteria**Sponsoring Committee**

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Current bylaws state that to qualify as a primary kidney surgeon, the proposed surgeon must document 15 total procurements, 3 of which must be multiple organ procurements. This requirement does not exist for any other organ group.

Progress To Date

Based on work group discussions for bylaw modifications to the same section where this is referenced, the MPSC will consider removal of this language during its March 2014 meeting. Should the MPSC agree, and the POC approve the concept, we anticipate Fall 2014 public comment. 5/19/14_Topic is closely related to other items to be reviewed by Joint Societies Working Group, and will be folded into those discussions. Anticipated public comment date (Spring 2015) has been modified accordingly. 7/22/14_JSWG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of multi-organ procurement requirements among other JSWG items to be discussed is TBD.

Possible Solutions**Policy Solution**

Remove requirement from kidney primary surgeon qualifications.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Consider primary surgeon qualification - primary or first assistant on transplant cases

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Most primary transplant surgeon pathways allow a surgeon to perform the requisite number of transplants “as primary surgeon or first assistant”. Therefore, an individual could qualify as the primary transplant surgeon for a transplant program even if they have never performed a transplant as primary surgeon before.

Progress To Date

This item was added as a "back log" item to address after the work group addresses higher priority items, likely in the next 6 months. 5/19/14: Project included in those topics to be discussed by the Joint Societies Working Group. This group will ultimately make recommendations for the MPSC's consideration. The JSWG roster was recently finalized as of May 2014. 7/22/14: JSWG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of primary surgeon primary versus first assistant requirements among other JSWG items to be discussed is TBD.

Possible Solutions

Policy Solution

Consider if there should be a requirement that a certain number of transplants used for qualification must be recorded as primary surgeon.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Consider requirement for primary physician observation of procurements

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Current bylaws state that to qualify as a primary physician, the physician should have observed at least 3 organ procurements and 3 transplants. SHOULD is not enforceable.

Progress To Date

no progress, this item is on the back log to be addressed after higher priority items have progressed. 5/19/14- This project was included in those topics to be discussed by the Joint Societies Working Group. This group will ultimately make recommendations for the MPSC's consideration. The JSWG roster was recently finalized as of May 2014. 7/22/14_JS WG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of primary physician observation of procurements requirements among other JSWG items to be discussed is TBD.

Possible Solutions

Policy Solution

Change "should" to "must" OR remove from bylaws

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Data Submission Accuracy and Supporting Documentation

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2014-March

Board Date: 2014-November

Status Post Public Comment

Problem Statement

Policy 18.1 requires members to submit data, but the policy does not explicitly state that the data must be accurate. The MPSC's position has always been that the obligation to submit accurate data is implied within the policy and has cited Policy 18.1 when taking action against members that have submitted inaccurate data. This practice is confusing for members, who often believe that they only have to submit the data in order to comply with Policy 18.1. Additionally, some policies require members to submit source documents for auditing or to maintain and provide documentation to the OPTN upon request. Members often assume that because the obligation to maintain documentation is explicitly stated within other policies, but not within Policy 18.1, that they are not required to maintain documentation to support the accuracy of their data submissions. As a result, OPTN staff and the MPSC often struggle to obtain relevant documentation necessary to determine whether a member is reporting inaccurate data.

Progress To Date

Discussed in meetings with Policy Director, Membership Assistant Director, and Assistant General Counsel. Presented to MPSC Chair during 9/24 chair call. Approved by POC and ExComm. MPSC discussed 12/12/13 and approved sending the language below for Spring 2014 public comment. (Bold added to show changes.) "Members must report accurate data to the OPTN using standardized forms. Table 18-1 shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor. Members are responsible for providing documentation to verify the accuracy of all data submitted to the OPTN through the use of standardized forms." Ready to go to March 2014 Public Comment. Part of non-discussion agenda for Spring 2014 Regional Meetings. Will be presented during National Webinars on March 18 and April 23. MPSC will be reviewing public comment feedback at its September 4th meeting.

Possible Solutions

Policy Solution

Add statement to Policy 18.1 that requires members to maintain documentation to verify the accuracy of data submissions, and to make the documentation available to the OPTN upon request.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Define "working knowledge" for primary physician qualification pathways**Sponsoring Committee**

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

The definition of working knowledge compared to the volume requirements for the primary physician shows some disconnect between the criteria for pre, peri, and post clinical involvement that is required for "currency", but the same clinical involvement is not necessary for each recipient followed to fulfill the volume requirement.

Progress To Date

The work group charged with addressing primary qualification bylaw requirements has identified at least 9 specific issues to consider. During the first meeting of the work group (11/2013), other topics were prioritized higher than this item. As of the March 2014 meeting, this item has not been reprioritized but should begin evaluation in the next 4 months. 5/19/14_Topic is closely related to other items to be reviewed by Joint Societies Working Group, and is currently planned to be folded into those discussions. 7/22/14_Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of working knowledge topic among other JSWG items to be discussed is TBD.

Possible Solutions**Policy Solution**

Pending further discussions

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Definition of a Transplant Hospital

Sponsoring Committee

Membership & Professional Standards

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

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.

Progress To Date

2010-2011: MPSC considered this issue. June 2011 MPSC Board report stated that "... the work group recommended that allowing separate hospitals to operate under a single program approval not be permitted. The committee voted unanimously to endorse this recommendation (33 For, 0 Against, 0 Abstentions) and instructed the work group to propose revised language defining transplant hospital and transplant program." HRSA was informed of this decision. Staff was informed that HRSA & CMS planned to publish a position on this issue in the Federal Register and request feedback. The project was reviewed by the POC and the Executive Committee in spring 2011. The POC scored the project low but the Executive Committee approved the project. During its December 2012 meeting, the Committee briefly discussed defining a transplant program. A working group was asked to address the definition of a transplant hospital and transplant program in order to work on the issue of health care systems operating multiple transplant programs in multiple hospitals under a single program approval. Issues such as policy and performance outcome compliance need to be addressed. Aug 2013 - Need to appoint new work group to restart the discussion. 11/21/2013: Work group met by conference call and started discussing what traits needed to be found in the definition of a transplant hospital. Decided a transplant hospital should not perform the same organ transplant in two geographically separated facilities except maybe for pediatric. 12/12/2013: This discussion continued at the MPSC meeting in Chicago. The realization is settling in that this issue is complex and requires a great deal of detail outlining so the impact of all recommendations can be recognized. 6/17/2014 MPSC approved proposed transplant hospital definition language for fall 2014 public comment.

Possible Solutions

Policy Solution

Potential solutions for exploration: Establish bylaw language which clearly defines - a transplant hospital as a single medical facility where transplants are performed; and -a transplant program as being designated for a transplant hospital. Complete Chrysalis Membership database redesign and allow for multiple transplant hospitals to be part of a single member medical system with the capacity to submit data for each transplant hospital performing the same organ transplants in the medical system.

IT Solution

New membership database providing options for subsetting member institutions into unique entities.

Instructional Solution

n/a

Other Solution

n/a

Evaluate Foreign Board Certification Bylaws for Primary Surgeons & Physicians

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

The bylaws do not provide specific guidance about how to determine which foreign boards are equivalent to the American Boards. Either a bylaw revision or an operational guideline is needed. The question has also been raised whether "foreign equivalency" should focus on possession of another country's specialty certification regardless of the level of training needed to obtain the certification, or completion of a training program similar in duration and difficulty to the one needed in the U.S. for board certification in that specialty.

Progress To Date

The work group has meet and discussed the need to clarify "foreign equivalency." Currently the work group is considering if foreign equivalency should even be an option for an individual to serve as a primary; this requires additional research and consideration of foreign medical and surgical boards. The work group will be discussing this topic during its March 2014 meeting though additional discussions with several foreign trained surgeons and physicians are expected for April/March. It may be necessary to review board certification requirements language for lab directors as well since that language mirrors that of the surgeons/physicians. 5/19/14_Project included in those topics to be discussed by the Joint Societies Working Group. 7/22/14_JSWG had its first teleconference (primarily focused on background and operational matters), and recurring teleconferences for JSWG are in the midst of being scheduled. JSWG agreed that its first topic of discussion would be Bylaws pertaining to foreign board certification.

Possible Solutions

Policy Solution

The committee will need to consider whether a bylaw change is needed or if the current bylaws are adequate and that operational guidance is needed so that there is a consistent interpretation of these bylaws.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Geographical Isolation BOD consideration

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2014-March

Board Date: 2014-November

Status Post Public Comment

Problem Statement

Making available a mechanism by which the MPSC can make a recommendation to the Board of Directors that the Board might consider designating and approving a transplant program which currently cannot meet key personnel qualifying criteria because the applicant is located in a prescribed geographically isolated area.

Progress To Date

This was discussed by the MPSC in the summer of 2012. The Committee asked the Executive Committee to approve releasing a proposal for special public comment. In December 2012, the Executive Committee declined to send the proposal to public comment and requested additional information. Ex. The Committee asked for a review of possibility of using or amending OPTN Bylaw D.10.F. Relocation or Transfer of Designated Transplant Programs to permit allowance of continuing prior approved transplant programs in a new hospital. Following this, the MPSC decided to follow the traditional path for policy development. The MPSC met during the summer and fall of 2013 to discuss the proposal. They decoupled this policy proposal from any pending membership applications. Staff also recommended not to use or modify OPTN Bylaw D.10.F for cases when the originating transplant hospital is closed. A proposal has been drafted for spring 2014 public comment. Spring public comment completed. Recommendations and comments were mixed. Public comment feedback will be addressed at September 2014 MPSC meeting and the proposal then will be presented to the Board at its December 2014 meeting.

Possible Solutions

Policy Solution

Propose this additional language to Appendix A Membership Application and Review, Section A.3 A.3.F.

Geographically Isolated Transplant Program Applicants The MPSC may recommend to the Board of Directors the approval of a designated transplant program if the prospective program cannot satisfy the current key personnel requirements due to its geographical isolation. Geographically isolated applicants must demonstrate to the MPSC that the proposed key personnel have both a satisfactory level of transplant experience and an established history of transplant success for the specific organ type indicated in the application for designated transplant program status. MPSC recommendation of approval of a geographically isolated program that is not otherwise qualified does not give interim approval to the prospective program. The designated transplant program status of a geographically isolated program that is not otherwise qualified is effective only upon approval of the Board of Directors. For purposes of this provision, "geographically isolated" is defined as a program located entirely within a state or commonwealth noncontiguous with the mainland United States. This includes, but is not limited to, Alaska, Hawaii, and Puerto Rico.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Primary Physician specialty & subspecialty board certifications

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

The bylaws require a primary liver physician to be board certified in gastroenterology. There are situations where a physician has active transplant hepatology board certification, but is not current with gastroenterology certification. The workgroup agreed that it seems reasonable to have the bylaws include subspecialty boards when primary board certification lapses. This is relevant for heart programs as well.

Progress To Date

Work group charged to consider this matter has an additional 8-9 topics relating to primary qualifications. This topic was prioritized lower than several others, though members agreed that the bylaws should include subspecialty boards. Additional discussion is needed, including considering the recent move to maintenance of certification (by boards). 5/19/14- Topic is closely related to other items to be reviewed by Joint Societies Working Group, and is currently planned to be folded into those discussions. This group will ultimately make recommendations for the MPSC's consideration. The JSWG roster was recently finalized as of May 2014. 7/22/14-JSWG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of this topic among other JSWG items to be discussed is TBD.

Possible Solutions

Policy Solution

Include subspecialty in board certification requirement will solve part of the problem. Still need discussion for the rest.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Primary Surgeon Procurement Requirement

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

For the primary surgeon to qualify a specific number of organ procurements must be documented. When qualifying under a fellowship/training pathway the applicable number of procurements all must occur in the two year training period. When qualifying under an experience pathway the applicant can combine the number of procurements performed during training and the experience period with no time restriction for inclusion.

Progress To Date

The work group recommended removal of the time limitations for surgeons trying to qualify through the training pathway. The MPSC will consider proposed bylaw modifications during its March 2014 meeting. 5/19/14- Project included in those topics to be discussed by the Joint Societies Working Group. This group will ultimately make recommendations for the MPSC's consideration. The JSWG roster was recently finalized as of May 2014. 7/22/14 JSWG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of primary surgeon procurement requirements among other JSWG items to be discussed is TBD.

Possible Solutions

Policy Solution

Remove two year limit for procurements obtained when applying for program approval through the fellowship/training pathway.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Quality Assurance & Process Improvement Initiatives

Sponsoring Committee

Membership & Professional Standards

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

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 MPSC reviews of member compliance and performance, the committee seeks to implement a similar requirement to further enhance OPTN member responsibility in facilitating quality improvement. The standard in the community is to have a quality improvement program (in part because CMS requires it) but there are still some institutions that do not have a quality improvement program, or may have a program that is not robust enough to satisfy MPSC concerns. The MPSC cannot enforce a community standard without placing it into policy/bylaws

Progress To Date

At its October 2013 conference call, the MPSC decided Committee review of a QAPI requirement would only be done in conjunction with a matter involving a policy or bylaw violation or a performance issue. No routine monitoring would be done. The Committee also felt that the language should be detailed enough to provide notice as to what was expected but not so detailed as to dictate member QAPI process. Sample language was requested for the 12/2013 meeting to use as a jumping off point for discussion. At the December 2013 meeting, the MPSC used sample language provided to spur discussion. The Committee then requested that proposed Bylaw language be provided for review by the Committee at its March 2014 meeting. At the March 2014 meeting, the MPSC approved proposed bylaw language for transplant hospitals and OPOs to go out for public comment in Fall 2014. There was further discussion of the monitoring plan that will be continued at the Committee's July 2014 meeting for inclusion in the public comment document. Proposed bylaw language for histocompatibility lab QAPI programs will be referred to the Histocompatibility Committee to consider in its rewrite of the bylaws. At a June 2014 conference call, the MPSC approved the proposed monitoring plan to be included in the public comment document.

Possible Solutions

Policy Solution

The MPSC recommends a bylaw requirement that all institutional members (OPOs, Histo Labs, and Transplant Hospitals) implement a quality assurance and process improvement program in their respective organizations and provide evidence of compliance and routine reviews of quality initiatives. The intent is to have the OPTN requirements similar if not mirror the CMS requirements and this bylaw would allow the MPSC to consider sanctions for members that do not have adequate quality management programs.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Reassess currency requirements for primary surgeons and primary physicians

Sponsoring Committee

Membership & Professional Standards

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Currency is defined in bylaw language in a way that is difficult to quantify and demonstrate compliance with appropriately. The definition does not specify a certain number of procedures that have to be performed, so the operational definition used is performing a single transplant (for surgeons) or caring for a single newly transplanted recipient (for physicians) within the prior two years. When reviewing applications where a proposed surgeon or physician has little to no recent transplant experience, MPSC members routinely comment that the existing definition is inadequate. The imprecise definition also makes it difficult for UNOS staff to advise members how they can achieve compliance with the requirement.

Progress To Date

The MPSC workgroup charged with this project has prioritized this item below several other topics to be addressed by bylaw modifications up for consideration during the March 2014 MPSC meeting. The work group agrees that defining "currency" as participation in 1 transplant/care of recipient in a 2 year period needs to be reconsidered however has not been discussed in detail based on more concerning bylaw issues be addressed first. It is expected that discussions for this topic will restart in the next 4-6 months. 5/19/14- This project is included in those topics to be discussed by the Joint Societies Working Group. This group will ultimately make recommendations for the MPSC's consideration. The JSWG roster was recently finalized as of May 2014. 7/22/14 JSWG had its first teleconference which primarily focused on background and operational considerations for moving forward. Recurring teleconferences for ongoing discussion are in the midst of being scheduled. JSWG decided the first topic of discussion would be Bylaws pertaining to foreign board certification. Prioritization of primary surgeon and physician currency requirements among other JSWG items to be discussed is TBD.

Possible Solutions

Policy Solution

Evaluate the existing currency definitions and compare their relevance to current medical practice. Attempt to develop quantifiable metrics that must be met to demonstrate currency, or at a minimum, develop a more precise definition of currency that can be consistently applied and easily explained to/understood by members. Possibly develop guidance for surgeons/physicians who do not meet the currency requirement that outlines the necessary steps for achieving compliance.

IT Solution

n/a

Instructional Solution

Instruction about any bylaw revisions would likely be a very small effort implemented primarily by Membership department staff. This would consist mainly of a Transplant Pro article to accompany the standard policy implementation notice. Instruction could also possibly include mention at the UNOS Primer following implementation of any bylaw changes. Any additional educational efforts would likely be performed by Membership department staff on an individual basis with member transplant hospitals, by answering questions from the hospitals or addressing the issue as needed during the membership application review process.

Other Solution

n/a

Guidance on Informed Consent for Living Donors Representing Vulnerable/High Risk Populations

Sponsoring Committee

Minority Affairs

Public Comment: N/A

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Some potential living donors are at greater risk of developing ESRD post donation. These potential donors often represent traditionally underserved and/or vulnerable populations and may be more susceptible to coercion and other pressures to donate, despite the risk. They are younger in age at donation and/or are ethnic minorities who are less likely to receive adequate information about their future health risks. Despite the known underlying risk factors for specific donors, there is no uniformity within individual transplant programs in how potential living donors are counseled about their risks. With the rapid growth of the kidney transplant waiting list, living kidney donors (LKD) have become an important source of organs. For a number of years, the OPTN Minority Affairs Committee (MAC) has been concerned about the safety of living donation for minority patients, particularly with respect to those individuals who donated their kidneys and may have ended up developing ESRD post-donation. A manuscript published by the MAC in 2011 showed that although the overall incidence of ESRD in living kidney donors is very low, black and male living kidney donors were significantly more likely than White and female living kidney donors to develop ESRD following kidney donation. However, the increased risks did not appear to be significantly higher than those seen in the general population. Regular updates on the status of the kidney paired donation pilot program (KPDPP) prompted renewed interest by the MAC in discerning minority living donor risks, as the practice of KPD is expanded and operationalized into policy. In 2013, the MAC viewed an unpublished manuscript presentation from a recent American Transplant Congress (ATC) meeting which proposed to better understand the risk of ESRD attributable to live donation through a comparison of ESRD incidence in live donors to their healthy matched non-donor counterparts. While black/African American donors had the highest absolute risk of ESRD, the study found that they had the lowest relative risk increase in ESRD when compared with healthy non-donors. The study reinforced the committee's research findings and concern regarding greater pre-donation risks in black/African American donors compared with white/Caucasian donors. While the MAC remains supportive of expanding minority access to living donation, it is also interested in ensuring that vulnerable donors at high risk fully understand their risk factors when being counseled about being a potential donor.

Progress To Date

Discussion and review of data during two committee meetings. Have received named subcommittee representatives from the Living Donor and Transplant Administrators Committees and await names of representatives from several other OPTN Committees.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

The MAC proposes to develop an educational resource that would provide guidance for defining a prospective living donor's potential and/or known risk factors, with talking points to counsel patients interested in considering living donation. The goal of the resource would be to standardize the discussion initiated with potential living donors with

specific risk factors, to help ensure that the practice of living donation remains accessible and safe as a transplant option. The MAC is collaborating with several OPTN committees, including the Living Donor Committee on the resource. The target audience for this educational guidance is providers with primary responsibility for initiating the informed consent discussion as part of the living donor evaluation.

Other Solution

TBD

The Patients Guide to Referral to Kidney Transplantation

Sponsoring Committee

Minority Affairs; Patient Affairs

Public Comment: N/A

Board Date: 2014-November

Status Evidence Gathering

Problem Statement

Minorities experience delays in referral, wait listing, and eventual transplantation as compared to Whites. Late referral has negative medical consequences for patients and limits future opportunities for successful transplantation. A majority of patients have seen a nephrologist < 12 months at time of initiation of dialysis. Many patients spend significant time on dialysis prior to referral for kidney transplant evaluation and many are never informed of transplant options. There is no established system to ensure that medically appropriate candidates are referred to transplantation. Late referral directly impacts the number of transplants as many patients who may have been suitable candidates initially, wait too long on dialysis and then lose the ability to be considered for a transplant. Late referral also impacts preemptive transplantation and contributes to excess patient mortality. The MAC formed a subcommittee to develop an educational initiative to raise awareness among referring physicians, practitioners and their national societies about appropriate and timely patient referral to kidney transplantation. This initiative resulted in the Educational Guidance on Patient Referral to Kidney Transplantation. The Guidance was intended to provide an opportunity for every medically eligible patient to be referred for transplantation for its survival and quality of life benefit. The Guidance document received Board approval in June of 2013. As the second phase of its work to improve referral, a joint subcommittee of MAC and PAC volunteers will use the content in the Guidance to develop a patient-focused brochure on ESRD referral. The subcommittee will be charged with 1) identifying the focus of the referral messages for patient education and outreach i.e., Why early referral is best What is early referral? Patients can self-refer (and information on how to do this) Basic information on the transplant evaluation and candidate waiting list process which would occur following a referral. Basic information on various types of transplants (deceased donor, living donor, KPD) How to create a workable social support structure to increase the likelihood of being considered as a transplant candidate and having a successful outcome following the transplant Overview of common barriers and how to overcome them both patient and provider Debunking common myths of transplantation (Things that are NOT a barrier to transplantation presented from the patient perspective) Patient self advocacy: how a patient can educate him or herself about transplantation and advocate for transplant candidacy, information/education about benefits of transplant, how to decide if transplant is the right choice, tips on how to talk to a provider to get questions answered. Patients can seek a second opinion about transplant candidacy if declined as a candidate at one transplant program FAQ's from the patient perspective 2) serving as SME's to translate the content in the document into targeted patient education and/or communication materials and provide assistance throughout the writing and development of the brochure. 3) recommending vehicles for dissemination of the information This work is occurring alongside the MAC project to provide educational/instructional programming on referral targeted to providers.

Progress To Date

February, 2014: Developed issue brief to solicit PAC joint subcommittee volunteers.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

A joint subcommittee consisting of MAC and PAC volunteers, with the assistance of the Communications Department, will use the content developed from the Guidance document to develop a patient focused brochure on referral to kidney transplantation.

Other Solution

n/a

Clarify requirements for blood type verification and align with CMS regulation where possible

Sponsoring Committee

Operations & Safety

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

Blood type verification for organ transplant compatibility is the most important way that donors and recipients can be matched for organs. Non-compliance with requirements for blood type verification of the organ donor and recipient continues to be a top deficiency for OPTN and CMS. The reasons for this non-compliance may be due to non-standardization of processes when carrying out the requirements of blood type verification policies, areas of vagueness in current policies, and inconsistent OPTN and CMS requirements for blood type verification.

Progress To Date

The Committee has had several meeting regarding this project. Staff and the Committee have taken a multi-prong approach to this project. Most notably, a Failure Modes Effects Analysis (FMEA) of the blood type verification process was completed by the ABO Verification Work Group of the Operations and Safety Committee to identify weak areas in blood type verification processes and policies. Staff worked to clarify terminology related to blood type verification requirements that could be addressed in the plain language policy rewrite for plain language. Draft blood type verification documentation forms were developed and provided to UNOS for reference in their work with CMS. Two ABO and other vital data verification forms template tools were developed in a collaborative effort of UNOS and CMS to aid Transplant Hospitals in developing processes and protocols for the documentation of compliance with both OPTN and CMS requirements pertaining to verification of correct organ for the correct recipient at two critical times – prior to living donor organ recovery and prior to organ transplant. These tools contain the required elements typically reviewed as part of CMS and UNOS routine survey activities and were made available in December 2012. This proposal was released for public comment on March 14, 2014. March-June 2014: Proposal out for public comment. Significant public comment received. Major themes include revisiting requirements for deceased donor organ recovery verification, general alignment with CMS, balance between prescriptive versus individual flexibility in policy, and requirements relative to error occurrences. ABO work group meeting to review comments and recommend responses and post-public comment changes for OSC consideration. At the June 26, 2014 meeting, issue related to continued allowance of deceased donor ABO determination through one draw and samples sent to two labs emerged. CMS and HRSA representatives present. OSC to obtain additional OPO feedback and reconvene on August 7, 2014 with CMS transplant and OPO representatives.

Possible Solutions

Policy Solution

The proposed solution will be to modify policy to cover areas of risk that may be identified through FMEA. The committee plans to address vagueness or inconsistency in current policies: Policy 3.1.2 - define the time period of "upon receipt and prior to implant" Policy 3.2.4 - Change current OPO requirement for completing both ABO tests on the donor "prior to incision" to "prior to match run" And is considering new policy requirements for: Specified information to review, verify, and document when the organ arrives at the transplanting center OPOs to upload donor blood type source documents in DonorNet for transplant center reference that would be beneficial in blood type verification when the organ recipient surgery must start prior to the organ arriving at the center OPOs to perform donor and recipient blood type verification prior to shipping organs when the intended recipient for that organ was not identified prior to organ recovery Addressing parking lot items identified through the policy rewrite project into the policy proposal Incorporating other issues as identified through the FMEA process into policy development There is a possibility that a proposed solution will require programming changes in UNet in the following areas: To collect blood type testing dates and times for system verification when a candidate and donor

are added; and Require verification of acceptance of a blood type incompatible transplant indicated in screening criteria. February 2014: The proposed public comment document would modify the following sections: Policy 1.2 (Definitions) Policy 2.6 (Deceased Donor Blood Type Determination and Reporting), Policy 2.6.A (Deceased Donor Blood Type Determination), Policy 2.6.B (Deceased Donor Blood Subtype Determination), Policy 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), Policy 2.6.D. (Secondary Reporting of Deceased Donor Blood Type and Subtype Policy 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), Policy 3.3.A (Blood Type Determination before Registration on the Waiting List), Policy 3.3.B (New: Initial Reporting of Candidate Blood Type), Policy 3.3.B (C) (Secondary Reporting of Candidate Blood Type) Policy 5.4.B (Order of Allocation), Policy 5.5.A Receiving and Reviewing Organ Offers), Policy 5.6 (Blood Type Verification Upon Receipt) Policy 13.6.A (Requirements for Match Run Eligibility for Candidates), Policy 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors) Policy 14.4. (New: Living Donor Blood Type Determination and Reporting), Policy 14.4.Ai (Living Donor Blood Type Determination), Policy 14.4.A.ii (Living Donor Blood Subtype Determination), Policy 14.4.A.iii (formerly 14.6) (Registration and Blood Type Verification of Living Donors before Donation), Policy 14.4.A.iv (New: Secondary Reporting of Living Donor Blood Type and Subtype Policy 16.1 (Organs Not Requiring Transport) Policy 16.4.C (Internal Labeling of Blood and Tissue Typing Materials)

IT Solution

Several proposed IT solutions: Add warning ABOi for liver candidate registrations (Spring 2014 PC) Add candidate blood type and ABOi symbol on match run view (Spring 2014 PC) Consider developing requirements for separate ABO tab Collaboration with ETT

Instructional Solution

Competency training (e-learning for ABO reporting and verification)

Other Solution

Future proposed solutions include: development of competency training, guidance and FAQs, consideration of development of separate ABO tab, and collaboration with ETT

Develop Policy to Address Safety Concerns Related to Large Volume Waitlist Transfers

Sponsoring Committee

Operations & Safety

Public Comment: 2014-September

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Current policy, 3.6.C Waiting Time Transfers, was not developed to address situations where a transplant center needs to transfer substantially all of their patients to another center(s). The committee believes that a policy solution is needed to address these situations instead of applying a policy that was never intended to be used for such circumstances.

Progress To Date

The committee has had discussions with the following committees to obtain their perspective of the issues related to large volume patient transfers and the safety issues associated with them: Patient Affairs Committee, Transplant Coordinators Committee, Transplant Administrators, UNOS organ center staff, and MPSC staff. The organ center staff has reviewed with the committee the different scenarios for waiting time transfer and how the process works, is documented and completed by UNOS organ center staff. The committee is drafting a tool kit to assist closing and receiving transplant hospitals. The Patient Affairs Committee is leading efforts to develop a section for patients. The tool kit will contain information on policy and bylaw requirements including patient notification items as well as sections for frequently asked questions and effective practices/lessons learned from other hospitals who have been involved with closing situations. December 2013 Discussed other programming solutions with IT. Currently, IT executes mass waitlist transfers via a data script. Since mass waitlist transfers are rare events, it was decided that it was not very beneficial in terms of cost and resources to explore other programming options. The group agreed that the current programming solution would continue to be used. February 2014: Draft public comment document in progress March 2014: Presented draft to MPSC to obtain feedback April 2014: Committee discussed proposal at in-person meeting. Committee requested additional language to have accepting hospital provide progress report to OPTN Contractor and additional data on number of long-term inactive, closed, and terminated transplant programs. May 2014: Modified draft language and obtained internal review. Added data as requested. June 2014: Committee voted to approve proposal to send out for fall 2014 public comment.

Possible Solutions

Policy Solution

The committee currently believes that proposed policy may need to address: Required blood type verification process that the accepting transplant centers should perform when adding transferred candidates to the waiting list Requirements for accepting transplant centers in processing wait time transfer forms

IT Solution

This proposal would authorize use of an IT solution to swap transplant hospital codes from the closing to the receiving transplant hospital. This IT solution has been used in the past with Executive Committee approval.

Instructional Solution

n/a

Other Solution

n/a

Develop system for review and sharing of safety events reported through multiple portals at UNOS

Sponsoring Committee

Operations & Safety

Public Comment: N/A

Board Date: N/A

Status Evidence Gathering

Problem Statement

There is currently no process developed within UNOS to share de-identified, real time information related to patient safety events with members, and at what level of granularity. Much data is collected at UNOS regarding safety events that happen in the transplant community, yet much of this information is not shared due to concerns of harming the medical peer review system in place. Because of these concerns, the learning that could benefit other centers and enhance patient safety is lost. The committee believes that members benefit from being aware of this information in the following ways: Enables centers to pro-actively resolve hazards before a tragic or costly incident occurs. Engages transplant staff at all levels in solving problems. Increases safety ownership and reinforces responsibility for patient safety. Exposes valuable information that otherwise might not be discussed. Develops a positive attitude surrounding safety in practice and reporting.

Progress To Date

The committee has reviewed safety events reported to UNOS since the implementation of electronic reporting in 2006 and proposed additional field categorization within the Improving Patient Safety reporting system in UNet to collect necessary information about reported events for DEQ investigation as well as committee data analysis and trending. Based on these efforts the Board approved a proposal in November 2011 to program additional data fields within the Improving Patient Safety reporting system in UNet. The addition of these field will provide for more effective and timely analysis of reported safety events. Business requirements are being developed before consideration of programming. May-November 2013 In response to concerns regarding use of extra vessels in non-transplant patients, the Committee has worked collaboratively with DEQ and MPSC to develop a process for issuing safety alerts to OPTN members. A safety alert on the extra vessels issues was developed using the new process and issued to members in November 2013. March 2014 The MPSC will initiate new process at meeting. Representatives from the Operations & Safety Committee (OSC) and Instructional Innovations will provide an overview of goals to share lessons learned without compromising peer review. At the end of MPSC meetings, general safety topic referrals will be made to OSC for evaluation and development of educational strategies. Staff and the committee are awaiting HRSA approval to work on a manuscript related to history and progress of safety reporting within OPTN. April 2014-June 2014 Referral stemming from concerns over living donor cases where positive infectious disease results were available but overlooked resulted in Patient Safety News article and regional meeting presentations to encourage transplant hospitals to examine internal process for potential fail points. Internal meeting on April 28, 2014 to discuss two potential topics for referral. Hemodilution issues to be referred to OSC for work. June 2014 Project approved to examine infectious disease verifications stemming from both MPSC referral and HOPE Act work group recommendations.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

n/a

Other Solution

Work with UNOS leadership, DEQ, Legal Counsel, and MPSC staffs to: Understand the benefit to the OPTN in sharing patient safety data with the membership; Develop a formalized process for collecting and analyzing safety data and how the data is shared with relevant OPTN committees; Explore how UNOS can promote safe reporting practices as used in the concept of "safe harbor" reporting systems.

Infectious Disease Verification Process to Enhance Patient Safety

Sponsoring Committee

Operations & Safety

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

While there is a clear process for ABO verification to prevent transplant of incompatible blood types (unless appropriate), there is no similar process of verification related to infectious disease. There have been cases where positive serology results have been available but inadvertently missed resulting in preventable disease transmission or near-miss of preventable disease transmission. This will become increasingly important as the Hope Act allows for the use of organs from HIV positive donors.

Progress To Date

This issue came up in a committee discussion related to their ABO verification proposal. It is expected that the FMEA completed for ABO verification will be useful in this effort as it also will include time outs at various points prior to organ implant. February 2014 The HOPE Act Safety subgroup had its first meeting on February 28, 2014. The concept of serology verification was mentioned as one potential safety step. Currently verification of serologies is required in OPTN policy for extra vessels and not on match run cases, but it is not specified as a requirement for all organs. The HOPE Act Safety subgroup plans to begin work on consideration of this potential requirement. March 2014 Due to HOPE timelines, this may move as separate project. April 2014 HOPE work group recommends to refer project to Ops and Safety June 2014 Project approved. Following ABO proposal in public comment as preliminary plan would be to use some or all same checkpoints for infectious disease verification

Possible Solutions

Policy Solution

Consider policy development to add requirements for infectious disease test results verification for donor and recipient and/or time outs prior to transplanting an organ.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Modify or eliminate internal vessel label

Sponsoring Committee

Operations & Safety

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

The sterile internal vessel label is frequently cited as a problem with the current labeling system. The very small label must be filled out in the sterile field where the sterile pen may run and make marking the label illegible. Up to 20 data fields must be handwritten. It has been noted that the internal label, having to be filled out in the sterile field using source documentation for infectious disease results, is often not as accurate as the external vessel label which can be filled out in an easier setting. Policies 5.4.3 and 5.10.2 (now in Policy 16 effective 2/1/14) require that vessels packaged separately from an organ be protected by a triple sterile barrier one of which must be a rigid container. The container and outermost barrier must have the OPTN standardized label. The sterile internal label is problematic to produce. This issue ranked as the 6th highest failure mode identified during the Failure Modes Effects and Criticality Analysis (FMECA) conducted by Northwestern University on the current deceased donor organ procurement process as part of the Electronic Tracking and Transport Project. The project will examine alternatives to the current practice to improve process while maintaining identification and information integrity for vessels.

Progress To Date

Recommendation received from Ad Hoc Organ Tracking Committee in June 2013. Project approved by POC/Ex Comm in Fall 2013. December 2013 Operations and Safety Committee has an ETT subcommittee now that the Ad Hoc Organ Tracking Committee no longer exists. The ETT subcommittee met on 12/2/13. Data request made at this meeting for safety situation reports related to either internal/external vessels labels. February 2014 Vessels data request completed and reviewed with ETT subcommittee on 2/26/14. This data included a review of patient safety situation data related to vessels packaging and labeling, disposition of extra vessels with attention to the percentage used in secondary recipients, and policy compliance data with vessels labeling. March 2014 The subgroup met March 20th to brainstorm possible alternatives to the current process in order to improve workflow, reduce error, and maintain safety. April 2014 Options discussed at April 8th OSC meeting. Additional option suggested for deliberation. May 2014 Subgroup met and plans to pursue education efforts on repackaging and proposed policy for reducing internal label to identifying info only. June 2014 Regular meeting schedule established. Next meeting 8/21/2014. Educational materials received to review and modify for upcoming efforts.

Possible Solutions

Policy Solution

The proposed policy would modify the requirements for the sterile internal vessel label.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

This project could require changes to the vessels labels distributed by UNOS.

Patient Safety Newsletter

Sponsoring Committee

Operations & Safety

Public Comment: N/A

Board Date: N/A

Status Evidence Gathering

Problem Statement

There is currently no other method for the OPTN to share real time data related to reported patient safety events. In sharing these data, there is heightened awareness of areas of safety concern. With the realization of these errors or failures that exist within the transplantation system, members can proactively review their policies and procedures to reduce harm to patients and improve outcomes.

Progress To Date

Operations and Safety has published four editions of its Patient Safety News newsletter since fall 2011. Each edition focusing on highlighting patient safety data recently reviewed by the committee as well as information related to hot topics in patient safety and organ transplantation. The Committee published an edition in September 2013. That issue featured a redesigned template. News stories will now be published on Transplant Pro in real time. A minimum of four stories will be published annually. Two of these will focus on the ongoing bi-annual patient safety situation data review. November 2013: Real-time article on 6 month data review published with link to full report January 2014: Article on EBV test kit issues published. February 2014: Article on reporting requirements to be published. March 2014: Article on Living Donor Evaluation safety written at request of MPSC. May 2014: Article on safety situation reporting, reporting system enhancements to be released 5/29/2014, and link to 6 month data report published.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

n/a

Other Solution

Continue publishing Patient Safety News at least twice annually to share patterns and trends related to safety events identified within the network.

Standardize an organ coding system for tracking of organs

Sponsoring Committee

Operations & Safety

Public Comment:	TBD
Board Date:	TBD
Status	Evidence Gathering

Problem Statement

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 creating issues related to organ transportation, transcription and data entry errors, and miscommunications that can lead to decreased organ utilization.

Progress To Date

This project was approved by the POC and Executive Committee in November 2011. In March – May 2012, UNOS staff & committee leadership visited centers utilizing ISBT 128. In September 2012, the Executive Director of ICCBBA (the company that developed ISBT 128) was invited to discuss how ISBT 128 could work for organ transplantation. In October 2012, an HHS Innovations Fellow was identified to work with UNOS on improving electronic tracking and transport of the nation's organ transplant system. UNOS was tasked by HRSA to implement a pilot project to design and test innovations in electronically identifying, labeling, and tracking organs from procurement through transplantation with the goal of identifying one or more feasible electronic methods to refine the current OPTN process of identifying and labeling organs during procurement and tracking organs during transport to transplant centers. The Ad Hoc Organ Tracking Committee was created with representation from stakeholders in blood banking, eye banking, OPs and Safety, OPO, TCC, TAC, and other applicable society representation to assist in accomplishing the work. The project was originally slated to end June 2013. A FMEA of the organ labeling and tracking process was begun in December 2012 and completed in March 2013 with all stakeholders in the labeling and organ tracking process. In collaboration with a UNOS Consultant and the HRSA Innovations Fellow, the OTC is now working to design a pilot study that will test the operation of the various approaches identified through the FMEA process. Once the pilot is completed, Operations and Safety will consider recommendations from the OTC on feasible system changes to implement. The pilot project was completed in June 2013. A final report and recommendations were presented to the Board of Directors in June 2013. This project will continue and has moved into the field testing phase for a stand-alone application using a tablet and portable printer to generate barcode (and human readable) labels for all phases of donor management and procurement. Plans are to continue development and eventually integrate this functionality into DonorNet. To date, two OPOs have started field testing following training and competency testing. The project scope also contains further development of a website where packaging and shipping information will be uploaded and provide some type of tracking functionality. The prototype also provides a mechanism for managing organ arrival and verification processes at the transplant hospital through scanning recipient and organ bar-coded labels. The current emphasis is on conducting field testing with the pilot site OPOs and further modifications to the prototype application. Discussions have started with UNOS IT staff regarding steps needed to integrate within DonorNet. Training has been conducted with five OPOs between July through December. All five OPOs have been conducting field testing. Two OPOs are still completing field testing. ETT project staff are working on requirements development and discussions with UNOS IT for integration with existing systems. The Operations and Safety Committee has an ETT subcommittee which meets to provide guidance on requirements, training, and other issues as needed. This subcommittee will also work on any policy proposals needed to implement ETT. Meetings have been held on 12/2/2013 and 2/19/2014. March 2014 Field test sites requested and obtained permission to continue field testing until beta version is available per recommendation of ETT subcommittee. April 2014-May 2014 ETT Project Team selected vendor to develop beta version. Requirements for beta version developed. UNOS IT involved in security and architecture structure development. June 2014 Beta version in development. Training for beta testing scheduled for September 10-11 in Richmond, VA and will include transplant hospitals as well as the original five field test OPOs and 3 additional OPOs. Regular meeting schedule for ETT subcommittee

set to meet monthly. Next meeting: August 21, 2014.

Possible Solutions

Policy Solution

Once recommendations from the OTC are available, vetted through the OPTN, and a system of delivery is agreed upon, policy will need to be reflective of the system design and requirements for its use.

IT Solution

It is envisioned that any system implemented with enhancements that allows for barcoding and collection of additional data will require a large programming effort with changes in DonorNet such as: Interfacing barcoding software with DonorNet for specified data elements Settings alerts for centers to notify them of when donor information has changes or new information becomes available Possibly provide access to information related to the GPS tracking of organs once released by the OPO

Instructional Solution

This project will require a large educational effort to instruct members on the use of the new system and policy requirements.

Other Solution

n/a

Deceased Donor Registration Form Completion

Sponsoring Committee

Organ Procurement Organization

Public Comment: 2014-September

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

There are inconsistencies in OPO reporting for donors that are consented/authorized but do not proceed to donation. Some OPOs will mark donors as "referral only" which stops the data collection process while others make a concerted effort to complete as much of the DDR form as possible. Because of the uncertainty about the percentage of actual cases that get reported and the inconsistency in the data that is collected, it limits the number and type of analyses that can be performed. It was also noted that the information being collected might not be accurate because OPOs do not always have all the information for validation purposes. One of the recommendations that came out of the Ad Hoc Organ Tracking Committee was to support the OPO Committee's effort to work on limiting the completion of the DDR to only actual donors which would take away the disincentive for delaying the generation of the Donor ID. This will allow for the Donor ID to be available for use on labels which could eventually include bar coding.

Progress To Date

The Executive Committee approved the project in November 2013. Conference call was held on January 30, 2014. The subcommittee agreed that policy language needs to be modified so that DDR completion is not required for non-donors. The subcommittee also agreed that modifications to the definition for deceased donor needs to be updated and recovered organ needs to be defined.

Possible Solutions

Policy Solution

The Committee is reviewing policy language to determine if changes are required. While the Committee agreed that information collected in the DDR should only be for actual donors, other means of collecting information on referrals that don't lead to donation could be done through the Death Notification Registration Form or some other means to be determined as the Committee works on this issue.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

HIV Organ Policy Equity Act Planning

Sponsoring Committee

Organ Procurement Organization

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

The HOPE Act will authorize use of HIV infected organs for transplantation into HIV infected recipients. The law requires that the OPTN revise its "standards of quality" no later than 2 years after the law takes effect. Currently no HIV infected organs are used within the OPTN and this law will necessitate a major effort to develop policy, procedures, and computer programming to allow for matching between HIV infected donors and recipients while preserving the safety and integrity of other organ transplantation functions.

Progress To Date

Initial conference call was held on January 31, 2014. Four subgroups were formed to address patient safety, allocation, labeling and electronic tracking and transplant and other policy areas. All four subgroups have met via conference call and reported to the full work group on April 2, 2014. Policy language and public comment document is being drafted in preparation for September 2014 public comment.

Possible Solutions

Policy Solution

Modify OPTN policies to allow the transplantation of HIV infected organs into candidates with HIV in accordance to the research protocols developed by the NIH. Modify OPTN policies to ensure adequate testing and donor/recipient protections are in place.

IT Solution

TBD - initial thoughts include DonorNet enhancements to allow reporting of NAT results and using future ETT programming.

Instructional Solution

n/a

Other Solution

n/a

Limit Paper Documentation Required to be included with Organ Packaging

Sponsoring Committee

Organ Procurement Organization

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

OPTN Policy 16.5.A requires that complete donor documentation be sent in the container with each transported organ. This often takes a coordinator hours to make copies of the large volume of documents that need to accompany each organ. This problem can be confounded when coordinators have to search inside hospitals to find a place to make these copies. Some documentation cannot be prepared until the donor is in the OR. These requirements originated prior to the availability of electronic medical records and functionality to upload into DonorNet. The added time required to make paper copies can lead to fatigue and potential errors and takes away from other donor management needs including organ labeling and packaging. This problem was identified during the immersion phase of the Electronic Tracking and Transport (ETT) Project while observing donor management and organ procurement practices in six OPOs and seven transplant hospitals. The OPO Committee recently received a memo from the MPSC requesting the review of paper documentation that is included with the shipment of organs.

Progress To Date

Operations and Safety Committee received recommendation from the Ad Hoc Organ Tracking Committee in June 2013. The project was reassigned to the OPO Committee in February 2014. OPO Committee has formed a subcommittee and will begin work on this in August 2014.

Possible Solutions

Policy Solution

Policy changes will be required and will depend on what the committees determines to be the best approach to reducing paperwork that gets transported with the organs. This could involve incorporation within the ETT project if that option becomes available for use.

IT Solution

Again, depends on the approach determined by the committee.

Instructional Solution

n/a

Other Solution

n/a

Define Pancreas Graft Failure

Sponsoring Committee

Pancreas

Public Comment: 2014-September

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

There is no standard definition for pancreas graft failure. Pancreas transplant programs reporting when a graft has failed varies due to no standard definition, limiting the ability to analyze and compare pancreas programs' outcomes.

Progress To Date

The Pancreas Committee's Outcomes Subcommittee has conducted a multiple teleconferences to focus on this topic. The members drafted a preliminary definition for pancreas graft failure in early 2013 but could not reach a consensus on the c-peptide aspect of the definition. During its June 5, 2013 teleconference, several Committee members shared their research findings on c-peptide criteria and methodologies utilized to collect the c-peptide values. The members decided that the current literature does not speak directly to c-peptide as it pertains to defining pancreas graft failure. The Subcommittee conducted a c-peptide data collection project where participating centers reported c-peptide values pre-transplant and at graft failure. As of May 2014 the Subcommittee has collected a sufficient amount of c-peptide data in order to begin analysis. The Subcommittee will analyze the data in order to determine an appropriate c-peptide value that indicates pancreas allograft failure. The Subcommittee analyzed the data from the c-peptide data collection project, at the Subcommittee's June 6, 2015 call. During the June 6, 2014 call, the Subcommittee review the data results and concluded there is inconsistent practice in how centers report pancreas graft failure. As such, the Subcommittee decided to omit the c-peptide prong from the previously proposed definition. Then the Subcommittee will look to the Tiedi Help Documentation and the remainder of the previously proposed definition to draft language for how to document pancreas allograft failure. From mid-June until mid-July the Subcommittee and other interested parties engaged in numerous email exchanges to discuss what thresholds should be accounted for in the new language for pancreas graft failure. The Subcommittee reconvened on July 15, further discussed the language, and voted on language for how to document pancreas graft failure. The updated language will be located in the Tiedi Help Documentation and Policy 1.2 Definitions - Graft Failure. UNOS staff will review the Outcomes Subcommittee's language, and provide edits, as needed. Then the full Pancreas Committee will vote on the final language at it's August 7, 2014 call.

Possible Solutions

Policy Solution

The definition for how to document pancreas graft failure will be located in the Tiedi Help Documentation as well as Policy 1.2 Definitions - Graft Failure. In addition, the Committee will propose to remove the "Partial Function" graft status category from the pediatric and adult PA and SPK data collection forms. The Committee will also propose to add additional fields to these forms.

IT Solution

To implement this solution it will be necessary to modify Tiedi for some additional data to be collected.

Instructional Solution

n/a

Other Solution

n/a

Pancreas as a Part of a Multivisceral (formerly "Pancreas for technical reasons")**Sponsoring Committee**

Pancreas

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

The problem this project aims to solve is a discrepancy in data and lack of policy surrounding multivisceral transplants. Specifically, the inconsistency between transplant centers and OPOs when reporting how a pancreas is transplanted during multivisceral transplantations. This inconsistency creates data discrepancies and inconsistent practices for post-transplant follow-up.

Progress To Date

The Committee leadership and corresponding Subcommittee have drafted definitions for multivisceral transplants. The Chair presented these definitions to the full Committee at its 10/8/13 in-person meeting. At the 10/8/13 meeting, the Committee voted on the following definitions and names for multivisceral and modified multivisceral transplant: (1) "Liver-Intestine-Pancreas Transplant" refers to a multivisceral transplant, and (2) "Intestine-Pancreas Transplant" refers to a modified multivisceral transplant. The Pancreas Committee gave updates to the POC regarding the status of this project on 10/23/13 and 4/16/14. In addition, the Pancreas Committee sent two representatives to the POC's multi-organ workgroup to ensure that the POC's multi-organ project did not conflict with the Pancreas Committee's Pancreas as a Part of a Multivisceral project.

Possible Solutions**Policy Solution**

Establish a definition for multivisceral transplant within policy that does not include pancreata where pancreata is solely transplanted for "technical reasons" (as opposed to be transplanted as a functioning organ).

IT Solution

The Proposed IT Solution may be non-existent or large depending on how the project develops. If the Committee decides to solely make changes to policy then the IT solution will be non-existent. However, should the Committee decide to make changes to the allocation system by changing how multiviscerals are categorized and allocated then the IT solution will be large. At this point it is too early to specifically pinpoint the size of the IT solution but the Committee will make a point to address this as the project develops.

Instructional Solution

As this problem stems from different perspectives as to how pancreata used for "technical reasons" should be accounted for, training to educate members on how this data is expected to be reported will likely be helpful.

Other Solution

n/a

Pancreas Underutilization

Sponsoring Committee

Pancreas

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

The goal of the Pancreas Underutilization project is to figure out why there is a decline in the number of pancreas transplantations and why a significant number of transplantable pancreases are not transplanted. The Committee will study data that may explain the trends in volume of pancreas transplants. The Committee will discuss everything from organ offer to implantation. This project will entail a broad look into allocation challenges, facilitated pancreas allocation updates, and issues from procurement to implantation (e.g. technical challenges, communication challenges, best practices). This projects includes the goals of two previously approved (but currently inactive and unresolved) projects: Investigating Sources from Pancreas Discards and Facilitated Pancreas Review. Regarding the Facilitated Pancreas Review aspect of this project, the facilitated pancreas allocation system only places a small number of pancreata (in 2008, 370 pancreata were offered through facilitated pancreas allocation and 35 pancreata were placed; in 2010, 298 pancreata were offered through facilitated pancreas allocation and 11 pancreata were placed). However, the numbers are significant enough that the Committee should allocate resources to revising the policy.

Progress To Date

Pancreas Underutilization Subcommittee members identified potential areas of improvement for Policy 11.7.A Facilitated Pancreas Allocation. These include: create criteria to participate in Facilitated Pancreas Allocation, create a monitoring process to monitor participating center's utilization of the Facilitated Pancreas Allocation, and perform a general review and update of Policy 11.7.A. Further, regarding the pancreas discards aspect of this project the Committee will convene to determine a specific vehicle for reducing pancreas discards (e.g. drafting a guidance document or best practices document, creating a pod cost, or releasing a webinar). The Committee discussed the path forward for this project at their 3/12 face-to-face meeting. Regarding Policy 11.7.A Facilitated Pancreas Allocation the Committee instructed the liaison to draft an updated version of the policy based on the previously identified areas of improvement. The liaison will be then present the draft policy to the Pancreas Underutilization Subcommittee and the Subcommittee will make changes as needed. Further, the Committee acknowledged that the Subcommittee will make data requests to assess the status of pancreas discards, then the Subcommittee will determine the specific path forward for how to address pancreas discards. At the 3/12 Committee meeting a Committee member volunteered to be the Pancreas Underutilization Subcommittee Chair. The Pancreas Underutilization Subcommittee has standing, monthly, calls until August 2014. The Subcommittee will discuss whether they need to hold additional meetings after August 2014. Thus far, the Subcommittee is in the research state where they have made two data requests and are in the midst of review the results of the second data request.

Possible Solutions

Policy Solution

The proposed solution is two-fold; it has policy and educational components. The first prong of the proposed solution addresses policy change including an update to the facilitated pancreas allocation policy.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

The proposed solution is two-fold; it has policy and educational components. The proposed solution is to produce a document that identifies why pancreata are underutilized, and if possible, identify effective practices to rectify the underutilization.

Require the collection of serum lipase for all pancreas donors

Sponsoring Committee

Pancreas

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

Policy Rewrite 2.8.E, Required Information for Deceased Pancreas Donors, lists the required information from deceased pancreas donors. This list of required information only applies to potential pancreas donors and currently does not include serum lipase values but does include serum amylase. Serum lipase analysis is more sensitive and specific, and thus a better indicator of pancreas quality. Further, Committee members have reported that during pancreas allocation some OPOs refuse to provide a serum lipase value. The data shows that members report serum lipase values in DonorNet for approximately 99% of pancreas donors (defined as pancreas recovered for transplant). This also shows that members report serum lipase values in DonorNet for approximately 79% of non-pancreas donors (pancreas not recovered). Overall, members report serum lipase values 83% of the time in DonorNet (all donors). Lastly, on the DDR members report serum lipase values for approximately 97-99% of pancreas donors, and for approximately 6% of non-pancreas donors. Members report serum lipase values on 24% of all DDRs. These numbers imply that roughly 17% of all donors (and 21% of non-pancreas donors) do not have serum lipase values available for consideration when making the decision to offer or place the pancreas for transplantation. Therefore policy 2.8.E should require the collection of serum lipase.

Progress To Date

At the Committee's October 2013 meeting, a Committee member asked if requiring the collection of serum lipase would be difficult for small OPOs. In order to further address this question, UNOS staff met with a Committee member (who is a subject matter expert on OPO operations) to discuss the OPO's perspective and to gather the OPO community input on the serum lipase project. The Committee member reached out to colleagues at small OPOs to inquire if the requiring serum lipase values would be burdensome. The Committee members' colleagues responded that it would not be a challenge if serum lipase became a required field and noted that he supports requiring serum lipase values if the test is available. The Committee member pointed out that the qualifying factor is if the serum lipase test is available, then it should be a part of required information for organ offers. The Committee member noted that there may be exceptional cases where a hospital may put in a place-holder value for a required field because, for whatever reason, they don't collect the required field. The Committee member noted that he wouldn't want the serum lipase requirement to be a limiting factor to send notifications. The Committee member expressed a concern that requiring serum lipase for electronic notification may delay organ allocation when a hospital is waiting on the lab value. Specifically, the Committee member noted the serum lipase value shouldn't delay the electronic notifications because the OPO should be able to proceed with the organ offers in order to sift through the uninterested programs. The Committee member noted that the issue isn't surrounding the interested programs; rather, the programs that are not interested in the offer. UNOS staff pointed out that serum amylase is currently required to send an electronic offer but is not required to run a match. Further, Pancreas Committee leadership want serum lipase to follow the same programming as serum amylase, and want a serum lipase value on the electronic notifications in order to determine the quality of the pancreas. The Committee member suggested for implementation purposes, it would be easier for OPOs to phase-in the requirement. Specifically, to require the serum lipase value in policy for auditing purposes, then at a later date, make the serum lipase field required in DonorNet®. The Committee sent the OPO Committee a memorandum that explains the serum lipase project, the benefits of the project, and how the project will affect the OPO community. The Committee asked for the OPO Committee's feedback and support of the serum lipase project. The OPO Committee recommended keeping serum lipase as a "desired or optional" piece of information along with the ranges, where the serum lipase values may be discussed at the time of the offer rather than becoming a required field. The OPO Committee suggested that if the transplant center has a question regarding a lipase value, the transplant center should communicate with the OPO or the on-site OPO personnel. Specifically, regarding the frequency of lipase

being documented for pancreas offers, the OPO Committee asked why serum lipase should be required when the data show the majority of OPOs report serum lipase values. Although the Pancreas Transplantation Committee understands the OPO Committee's point, labs do not report serum lipase values 100% of the time, and since the value is a direct indicator of pancreatic quality, it should be reported every time, without exception. Specifically, regarding reporting the upper limit of normal value, the OPO Committee suggested reporting this value only if it is available. In response, the upper limit of normal value is an existing number that is associated with the serum lipase test the lab chooses to use. In other words, the upper limit of normal value is available every time the serum lipase test is performed. Since serum lipase values are a direct indicator of pancreatic quality, the serum lipase value should be reported for every offer. In addition, from a data analysis perspective, collecting information about the upper limit of normal will allow for the lipase values to be normalized and combined across OPOs with varying 'normal' ranges. Lastly, the OPO Committee did not support another mandatory field in UNetSM, especially one that requires additional programming to add real time normal ranges for each donor. Although the Pancreas Transplantation Committee understands that this proposal creates additional responsibility for the OPO the majority of labs are already reporting the value to the OPO. Therefore, the need for the value outweighs the additional administrative burden and costs considering that serum lipase values directly reflect pancreatic quality. The POC voted to recommend (to the Executive Committee) to send the proposal out for public comment on 2/7/14. The Executive Committee voted to send the proposal out for public comment on 3/5/14. Committee leadership and UNOS staff have reviewed all feedback from public comment. Overall, the public comment feedback is positive. However, the OPO community has expressed concern over making serum lipase a required field for OPOs that are located in geographically remote areas. One individual in the OPO community suggested to allow OPOs in geographically remote areas additional time to provide the serum lipase values for electronic pancreas offers. The Pancreas Committee is looking into ways to address the OPO community's concern. The Pancreas Committee leadership will reach out to individuals in the OPO community during July 2014. The Pancreas Committee will meet with OPO Committee leadership in August 2014 to provide an update on the project's status. The Pancreas Committee will then give a final update to the OPO Committee at its fall meeting on September 23, 2014.

Possible Solutions

Policy Solution

Require that OPOs collect serum lipase for all pancreas donors.

IT Solution

There are two potential IT solutions. The first option is to make serum lipase, a field that is already programmed and exists in DonorNet®, a required field. This first option requires a small amount of programming efforts since the serum lipase field already exists. The second option is, in addition to making serum lipase a required field, to create an additional field, the "upper limit of normal". The "upper limit of normal" field will be a field where centers will enter the upper limit of normal corresponding value for the serum lipase test they use. The programming of this additional field will require more programming efforts and complexity.

Instructional Solution

n/a

Other Solution

n/a

Review Pancreas Primary Physician/Surgeon Bylaws

Sponsoring Committee

Pancreas

Public Comment:	2015-March
Board Date:	2015-November
Status	On Hold

Problem Statement

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

Progress To Date

The Bylaws Review Subcommittee met every other week, for one-hour increments, beginning 11/8/13 until 1/10/14. After 1/10/14 the Subcommittee met once a month to continue working on the project. Specifically, the Subcommittee is discussing creating a combination pathway for achieving the primary surgeon and physician requirements. The combination pathway will be in addition to the fellowship and experience pathways. The Subcommittee has drafted language to clarify the multivisceral requirements for when a pediatric pancreas is transplanted with a pediatric multivisceral under the alternate pediatric program requirements. Lastly, the Subcommittee is discussing updating the surgeon and physician requirements for islet programs. The Subcommittee gave an update to the MPSC at it's December 2013 MPSC meeting. The Subcommittee gave a brief update to the Pancreas Committee at the Pancreas Committee's 1/22/14 teleconference. The Subcommittee reached out to a CIT Steering Committee representative and invited the CIT Steering Committee to provide feedback on the Subcommittee's work on the islet section of the OPTN Bylaws. The Subcommittee also invited the CIT Steering Committee (or a representative) to attend on of the Subcommittee's monthly meetings to share the CIT Steering Committee's feedback. The Subcommittee presented its progress-to-date to the full Pancreas Committee at the Committee's 3/12/14 meeting. The Committee voted, in support, of one clerical change to the Pancreas Bylaws. The Subcommittee's goal was to have a final, updated, draft of the Pancreas and Islet Bylaws to release for Fall 2014 public comment. However, the Joint Societies identified this project, along with five others, that a Joint Societies Working Group (JSWG) will review. This project is currently on hold and awaiting the JSWG's review and recommendations. After the JSWG provides its recommendation on this project the Subcommittee will re-convene to review and incorporate the JSWG's recommendations.

Possible Solutions

Policy Solution

The Bylaws Review Subcommittee is reviewing several sections of the Pancreas and Islet Bylaws in order to update the requirements and make clarifications as needed. In particular the Subcommittee is drafting new language for the Primary Pancreas and Physician procurement requirements, the alternatives for pediatric programs, and islet program and personnel requirements. At this stage the project does not entail changes to the Pancreas policies.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Clarify Policy Language and Process for Individual Wait Time Transfer

Sponsoring Committee

Patient Affairs

Public Comment:	2015-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

Current Policy 3.2.1.9 Waiting Time Transferral, does not outline all of the responsibilities between transplant hospitals in wait time transfer. It further, does not provide a clear explanation of the process for wait time transfer. This silence in policy has resulted in inconsistencies in the application of the policy between transplant programs and within the Organ Center as well. It further creates scenarios where wait time transfer in like situations for the same organ may be applied differently, resulting in potential disenfranchisement for individual patients.

Progress To Date

3-2014 Staff from the Operations and Safety Committee and the Organ Center have reviewed the Organ Center processes for wait time transfer. The frequency of requests and the average amount of time required to complete a wait time transfer request were established. The Operations Committee is collaborating on this project to insure that the policy language will mirror the language and intent of OPTN Bylaw Appendix K. Review of the Wait Time Transfer Process among 6 transplant programs presented to the Committee showed discrepancies in process and in interpretation of policy and in intent for transfer. A discussion with organ-specific liaisons established consensus on the need for clarification of policy language. The goal is to compare of proposed changes with the current Policy Rewrite Project language changes. 4-23-2014 Primary responsibility for policy development for this project was assigned to PAC in February 2014. Since that time, the Committee Liaison and Research Liaison have been in consultation with the leadership of the Policy Department, and management for the Organ Center to clarify and expound upon the scope of the problem and potential and reasonably attainable solutions. We suppose, based upon discussions within the group, that any solution will involve programming. To that end, a business analyst has been added to the group. The management of the Organ Center have developed a written outline of the decision making process currently utilized in Wait Time Transfer. The BA and the Committee Liaison have observed the wait time transfer process in the Organ Center. Currently, the management of the Organ Center and the Research Liaison are reviewing the last 500 wait time transfer requests in an effort to identify patterns or problems with wait time transfer requests and resolutions that might help to answer this fundamental question. Do the issues inherent in the current wait time transfer process warrant a policy change; or can they best be addressed by some type of formal procedural guidance? 5-20-2014 The internal workgroup met on 5/2/2014 to review a spreadsheet of the last 500 wait time transfer requests. Research provided an overview of the layout and content of the spreadsheet. The workgroup is to review the data to begin to categorize the data into the most common types of requests and potential outliers. This will allow the group to suggest policy language. The group reconvenes tomorrow, 5/21/2014 to review all feedback and make decisions. Staff have begun developing key points to the proposal for consideration by the group and developed a list of goals for the internal group to consider. The next steps are: 1) Develop subcommittee 2) Present proposed workplan to PAC and get input 3) Define IT components of proposal. 7-11-14 This proposal will not require programming at this time. The policy language is being clarified. 7-22-2014 Draft policy language has been presented for internal review.

Possible Solutions

Policy Solution

Clarify the policy language and the process for wait time transfer in Policy 3.6.C

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Pediatric to Adult Care Transition Project

Sponsoring Committee

Patient Affairs

Public Comment: N/A

Board Date: N/A

Status Evidence Gathering

Problem Statement

Adolescence is one of the healthiest periods in the lifespan. On the other hand adolescents exhibit the highest rates of risk-taking behaviors and potentially life-threatening consequences. Available literature, data and practical clinical experience confirm this pattern in the transplant community where adolescents have a higher rate of graft loss than any other group. Long Term outcomes for teens between the ages of 11 and 19 show higher rates of acute rejection, graft loss and mortality. A review of available graft survival 5 years post-transplant shows an average of 25-30% graft loss occurs between the ages of 11 and 34. A review of data on candidates who received transplants in 2010 shows the highest rates of re-transplant occurring in the 26 to 34 year-old age group. It can, then, be inferred that these patients lost their initial graft in their late teens or early 20's, during the time when transition to adult care would be expected to occur. Transition is defined as an active process that addresses the medical, psychosocial, and educational/vocational needs of adolescence as they prepare to move from child-centered to adult-centered care. By contrast, transfer is the actual act of relocating care from one provider to another. Dr. A.R. Watson first identified a correlation between graft loss in the teen years and transition from pediatric to adult care in a study published in Pediatric Nephrology in 2000. Shaw, Palmer et al (Ped. Trans. 2003) relate a correlation between adherence and graft loss, while Chaturvedi et al (Ped. Neph. 2009) propose that 44% of graft loss among teens occurs during the transition from pediatric to adult care. This phenomenon of increased incidence of graft loss during transition to adult care, resulting in potentially results in the following: increased risk to the health and well being of young patients who are already living with chronic illness loss of otherwise healthy grafts with a significantly longer survival rate due to non-adherence decrease in grafts available to other, potentially, first-time candidates longer wait times for these candidates after being re-listed increased possibilities for death on the waiting list

Progress To Date

The Committee has completed a thorough review of the literature and reviewed available transplant data. The Committee has also reviewed existing transition resources from the HHS Maternal and Child Health Center for Transition Improvement and resources currently available through the AST Pediatric Community of Practice. This project replaces the current Teen Adherence Project (TAP). The Transition Project provides a more focused approach to addressing the underlying problem of non-adherence among teenagers. January, 2014: Staff is working with the UNOS Communications Dept. to update the current Pediatric page on www.transplantliving.org to include relevant information on transition. March, 2014: Staff is meeting with the UNOS Education and Communications Depts. to establish goals for both print and online education for patients and profession on Pediatric Transition. There will be a discussion at the upcoming PAC meeting to get the patient perspective. April, 2014: UNOS Communications is finalizing their proposal for the Pediatric Transition Page. Plan to present to the Subcommittee in May and to the full committee in June, with goal of final implementation by July 1, 2014 May 2014: The Subcommittee will meet to hear options for developing the Pediatric Transition page on www.transplantliving.org July 2014: Communications is developing language for the Transplant Living Website.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

Develop patient focused transition resources as companion pieces to the clinical resources developed by the AST Pediatric Workgroup.

Other Solution

n/a

Update 'What Every Patient Needs to Know' Brochure

Sponsoring Committee

Patient Affairs

Public Comment: N/A

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

'What Every Patient Needs to Know' is one of the premier educational resources designed and distributed by UNOS. The last update was in 2010. Since that time there have been several significant changes in the transplant community (KPD, ILDA's, New KAS) etc which should be added or updated. Historically, the Committee has taken the lead in this project.

Progress To Date

Current book exists. Since WEP was last rewritten in 2010, there have been significant policy updates and changes within the OPTN that impact the target population for this resource; e.g. implementation of KPD, updated and new living donor guidelines, adoption of the new KAS, changes to Wait Time Transfer and Inactive Wait List status. These changes warrant updated language within WEP. 7-22-2014 - FW Committee Leadership and Committee Staff have met with Communications and Instructional Innovations to develop a preliminary timeline for this project. Efforts have begun to identify areas within WEP that require an update. The next consult with Communications is scheduled for 7/24/2014. A Subcommittee will be formed at the August Full Committee Conference Call.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

This project will entail updating specific sections of the existing WEP to better reflect current policy and practice. This will not be a total rewrite of the book.

Other Solution

n/a

General Principles for Pediatric Allocation

Sponsoring Committee

Pediatric

Public Comment: N/A

Board Date: 2014-November

Status Evidence Gathering

Problem Statement

In June 2010, the OPTN/UNOS Ethics Committee published “Ethical Principles to be Considered in the Allocation of Human Organs,” which presented utility and justice as two ethical principles that must be balanced in order to achieve an equitable allocation system. The National Organ Transplant Act (NOTA) charges the OPTN to “recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.” The OPTN/UNOS has never publicly articulated the special ethical considerations when developing organ allocation policy for pediatric patients. In 2013, the Chairs of the OPTN/UNOS Pediatric Transplantation and Ethics Committees recognized the need to present an ethical justification for pediatric priority in an equitable allocation system.

Progress To Date

This idea was originally introduced at the Committee's meeting on September 24, 2013. The Joint Subcommittee held its first teleconference on 1/8/14. Discussion resulted in a first draft white paper of ethical principles to justify pediatric priority. Subsequent meetings were cancelled due to a lack of availability. The Joint Subcommittee met on 6/17/14. Discussion resulted in a second draft white paper, which was submitted for the full group's consideration on 7/16/14. The next call is scheduled for 8/7/14.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

n/a

Other Solution

The Joint Subcommittee eliminated a guidance document as a potential solution when members concluded that they would not make organ-specific policy recommendations.

Pediatric Classification for Liver Allocation

Sponsoring Committee

Pediatric

Public Comment: 2014-September

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Policy 9.3.A says "Liver candidates with a MELD score initially registered on the waiting list when less than 18 years old who remain on the waiting list or are registered again after turning 18 years old may be assigned the appropriate pediatric classification by exception. The transplant hospital must apply for the exception and include justification to the applicable RRB..." However, once age 18, regardless of whether the patient was on the list prior to age 18, the system does not allow a candidate to appear in a pediatric classification other than pediatric 1A or pediatric 1B (i.e., MELD candidates 18y/o and older with an RRB-approved pediatric classification do not appear match runs as a pediatric candidate, eligible for pediatric donor priority). This functionality was removed in 2005. At the time the project was submitted to the POC, there had only been 2 instances when this priority was requested by a center, once in 2005, and once in 2012. This programming concern was fixed in 2013, but Committee discussions about this issue led to a decision that the policy language should be changed. Current policy (9.3.A- Pediatric Status Exception for Candidates 18 Years or Older) requires pediatric liver candidates with a MELD score who remain on the waiting list after their 18th birthday to submit a request to the Regional Review Board if they wish to retain their "pediatric classification." A Regional Review Board request is not necessary if the candidate is listed as Status 1A or Status 1B. Similarly, pediatric liver candidates who were removed from the list (for whatever reason) but have returned to the list after their 18th birthday, may request "pediatric classification" from the Regional Review Board. If these candidate meets pediatric Status 1A or pediatric Status 1B criteria, then Regional Review Board approval is also unnecessary. As currently organized, the Committee believes there are two problems. 1) Eliminating a candidate's "pediatric classification" the day of their 18th birthday is inconsistent with how other organs (i.e., kidney, heart) treat "pediatric classification." 2) With the exception of a previously listed pediatric liver candidate who returned to the list after their 18th birthday, the Regional Review Boards have approved every submitted pediatric classification request (10). As such, the Committee believes this is an inefficient use of Regional Review Board resources.

Progress To Date

The programming has been fixed to allow the match to operate as dictated in policy. The Committees will review the policy to determine if any changes should be made. Educational efforts are underway. December, 2013: The Pediatric Committee discussed potential policy changes so that every candidate who remains on the waiting list after their 18th birthday would continue to be classified as a pediatric liver candidate. Additionally, the option to request pediatric classification for pediatric liver candidates who have returned to the waiting list after their 18th birthday would be eliminated. A memo has been drafted for the Liver Committee to get its feedback on these potential changes. March, 2014: The Liver Committee discussed this matter during a February teleconference. The discussion was generally supportive, and the Liver Committee provided additional feedback for the Pediatric Committee to consider. The Pediatric Committee will review this feedback at its April 2014 meeting. April, 2014: Pediatric Committee discussed at in-person meeting. The liaison will consult with the Liver Committee to determine if this will be on-track for Fall 2014 Public Comment in light of redistricting. June 2014: The Pediatric Liaison met with UNOS Support Staff, including Organ Center staff, the Liver Committee Liaison, and the Liver Committee Research Liaison, to discuss the need for this policy and the feasibility of implementing the proposed solution. The Pediatric Liaison observed the RRB Manager to understand the current process for approving a pediatric classification exception. She confirmed the Pediatric Committee leadership's interest in having this proposal go out for Fall Public Comment. The Liaison met with the Policy Editor, the Assistant Director of the Organ Center, DEQ staff, and the Policy Director to write revised policy language. The entire UNOS Support Staff finally reviewed the language and delegated responsibilities for the draft Public Comment Proposal. July 9, 2014: The Pediatric Liaison met with Committee leadership in the morning to review the proposal in preparation for the day's vote. The full Committee met in the afternoon and voted

to approve the policy (14, 0, 0 with the support of the Liver Crossover Representative, who could not be present for the call). The Liaison is now drafting the Public Comment proposal.

Possible Solutions

Policy Solution

The Pediatric Committee has discussed potential policy changes so that every candidate who remains on the waiting list after their 18th birthday would continue to be classified as a pediatric liver candidate. Additionally, the option to request pediatric classification for pediatric liver candidates who have returned to the waiting list after their 18th birthday would be eliminated. The Committee (and thus, likely most of the community) was under the impression that this is how pediatric liver classification already worked.

IT Solution

If these policy changes were adopted, programming would be needed so that every pediatric liver candidate remaining on the waiting list after their 18th birthday would automatically continue to be classified as a pediatric liver candidate.

Instructional Solution

I do not know that this will require IT -- but explaining this to the community may take some effort.

Other Solution

n/a

Pediatric Transplantation Training and Experience Considerations in the Bylaws

Sponsoring Committee

Pediatric

Public Comment: 2015-March

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

Pediatric transplantation is a specialty within the field of transplantation; however, the Bylaws are silent regarding any pediatric training and experience requirements. As such, transplant hospitals that predominately serve pediatric candidates may have professionals without ANY pediatric transplant experience approved for key personnel roles (primary surgeon, primary physician). A secondary issue associated with this larger problem is that the Bylaws do not define what constitutes a pediatric transplant program.

Progress To Date

The Pediatric Committee, and its organ-specific working groups, have had numerous conversations about this topic. Considering the "potential controversies or barriers" listed above, a variety of approaches and possible solutions have been discussed. The Committee believes that all pediatric transplant candidates at every transplant center should receive the same quality of care assurances; however, it is sensitive to previous unsuccessful efforts to address this problem, and believes some progress must be made. Instead of relying on historical accounts and inferring how the community may respond to any proposal, the Committee thought it was prudent to solicit feedback from the community prior to moving forward with any recommendations (via the issue brief mentioned in "collaboration with others"). The Committee intends to take the feedback it receives to finalize its recommended solutions. The Committee met in January 2014 to review feedback received at fall 2013 regional meetings. In response, the Committee simplified its recommendations and plans to present these at the spring 2014 regional meetings. These updated recommendations will also be sent to the organ-specific committees for their feedback. ASTS Executive Committee requested call with Pediatric Leadership for May 22. ASTS cancelled the call on May 19 but plans to reschedule. On June 17, 2014, Committee leadership met with the ASTS Executive Committee, at their request, to discuss their feedback on this proposal. The ASTS Executive Committee requested time to convene a working group to provide more specific recommendations for revisions to this proposal. Committee leadership agreed to consider more specific recommendations and requested that they be submitted by August 20, 2014 for discussion at the full Committee meeting on August 26, 2014 in Chicago. Incoming Committee leadership is committed that this proposal will go out for Spring 2015 Public Comment and will go to the Board in June 2015.

Possible Solutions

Policy Solution

The Committee is asking for feedback on two possible solutions for two individual problems. 1) Define pediatric transplant program a) a definition modeled after CMS: a pediatric program would be defined as one that does 50% or more transplants in pediatric patients over a 12-month period. b) any program that does a pediatric transplant would be considered as having a "pediatric component" which would introduce additional "pediatric key personnel" roles. 2) Training and Experience Requirements for key personnel at a "pediatric transplant program" - a) 50% of cases submitted to meet the current key personnel requirements must be pediatric transplants b) new, additional pediatric case volume considerations that would be required along with the current key personnel requirements. It is important to note that the "pediatric pathway" for each respective organ will remain regardless of the solution pursued. Its inclusion is imperative to allow individuals who do not meet the explicit Bylaw requirements, but would otherwise be thought of as qualified, an opportunity to serve these key personnel roles. The Committee is recommending that every kidney, liver, heart, and lung transplant program that intends to transplant patients younger than 18 years of age must have an approved "pediatric component." An approved pediatric component would only entail formally recognizing qualified individuals involved with the transplant program as the "pediatric

primary surgeon” and “pediatric primary physician.” Individuals meeting the recommendations (that are being finalized) would be deemed qualified by the MPSC to serve in these roles.

IT Solution

The membership database needs to be updated to accommodate tracking "pediatric components."

Instructional Solution

Current bylaws include requirements that apply to all transplant centers and do not differentiate between adult and pediatrics. Any adopted solution will include completely new bylaws that explicitly recognize pediatric transplantation. As these new requirements will be a formal shift in the way programs are viewed by the OPTN, an additional training session to review and reiterate the changes and their implications will likely be prudent- in addition to the standard policy/bylaw implementation processes. Educational needs will continue to be monitored. An alert/communications/awareness effort may only be needed based on public comment and Board outcomes.

Other Solution

n/a

Clerical changes to policy

Sponsoring Committee

Policy Oversight

Public Comment:	2014-March
Board Date:	2014-November
Status	Post Public Comment

Problem Statement

Staff receive requests to make clerical changes to policy (ex. misspellings). The Bylaws do not provide a mechanism for changes to policy outside of the Executive Committee or Board. Most state laws provide a mechanism for an administrative agency to make these non-substantive corrections to policy outside of their normal policy development process. These requests are rare (single digit requests per year). Historically, any requested changes that could potentially change the meaning of the policy are sent to the Executive Committee or Board for review.

Progress To Date

Staff researched similar laws in other states regarding clerical (non-substantive) changes in their administrative codes or regulations. The POC approved policy language for public comment. This proposal was released for public comment on March 14, 2014. Public comment resulted in no controversy or identified problems with the proposal. As such, this proposal will go to the BOD for approval in November 2014.

Possible Solutions

Policy Solution

We will add a new section to Bylaw Articles X (Amendment of Charter and Bylaws) and XI (Adoption of Policies) that permits staff to make clerical, non-substantive changes to the bylaws and policies. It will contain a limited list of permissible changes. The proposal will include a review mechanism by the Executive Committee. The current proposed language is: 11.7 Non-Substantive Changes to Policy The OPTN Contractor may correct any of the following: Capitalization or punctuation, as needed to maintain consistency with current policy Typographical, spelling, or grammatical errors Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited. The Executive Committee will retrospectively review any corrections made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Definition of the End of a Transplant

Sponsoring Committee

Policy Oversight

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

Policy defines when a transplant begins, but it does not specify when a transplant ends. This lack of clarity can create a reporting problem for transplant programs about whether an event took place during or after the transplant ended. Without a clear definition in policy, transplant programs will report adverse events inconsistently, and UNOS staff will not be able to monitor these events consistently. Additional clarity may also be needed on the transplant date of a multi organ transplant that occurs over the course of two days.

Progress To Date

Staff has developed potential scenarios where this lack of definition poses a problem in reporting and has developed draft language for the committee to review. The completion of the transplant procedure is defined as one of the following: (1) the chest and/or abdominal cavity is closed and the final skin stitch and/or staple is applied, (2) the recipient leaves the OR (in cases where the recipient's abdominal or thoracic cavity is not closed), or (3) the islet cell infusion is complete. The POC reviewed and voted on proposed language at its April 2014 meeting. It is going out for public comment fall 2014 as planned.

Possible Solutions

Policy Solution

The proposed solution is to define the end of a transplant in policy as follows: 1.2: Definitions Organ transplant
Organ transplants include solid organ transplants and islet infusions. An organ transplant begins at the start of once any initiation of organ anastomosis has taken place during the intended transplant or the start of an islet cell infusion. An organ transplant procedure is complete when either one of the following occurs: The chest or abdominal cavity is closed and the final skin stitch or staple is applied. The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed. The islet cell infusion is complete. Transplant date Determined by the start of the organ anastomosis during transplant or the start of the islet infusion beginning of organ anastomosis. For a multi-organ transplant procedure, the transplant date for each organ is determined by the transplant date of the first organ transplanted.

IT Solution

The only programming that would be required is to update help documentation.

Instructional Solution

If approved, there would need to be an educational initiative to inform transplant programs about the new policy definition. This would be a large effort because it would change the way transplant programs have been instructed to report multi organ transplants.

Other Solution

n/a

Geographical Disparities in Organ Allocation

Sponsoring Committee

Policy Oversight

Public Comment: N/A

Board Date: 2013-November

Status On Hold

Problem Statement

The issue of addressing geographical disparities in organ allocation is one of the key goals outlined in the OPTN Strategic Plan that was approved by the Board of Directors in June 2012. The ultimate goal of addressing this issue is to identify and eventually come up with equitable allocation and distribution to best meets the needs of the patients. The first step could be to evaluate current allocation algorithms and determine if they are appropriate in their current format or perhaps could be enhanced to promote a broader distribution of organs in a measurable manner that is associated with an improved outcome. The issue of geography is explicitly stated in the Final Rule. "§ 121.8 (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." It was noted that the Advisory Committee on Transplantation approved a recommendation in 2010 that states organ allocation should be evidence-based and not based on the arbitrary boundaries of DSAs or OPOs.

Progress To Date

May/2014 The POC will contribute to the concept document that will be distributed to introduce the liver redistricting solutions. The POC will continue to ask the other organ specific Committees to report on their progress on establishing metrics. The POC will not provide further input to the Executive Committee on this subject until the Liver redistricting is rolled out and the reaction and acceptance of it is assessed. November 2013- Provided answers to the key questions to address geographical disparities to the Board at the Nov meeting. The Board directed the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013. The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represent patient outcome. The POC presented these metrics to the Board at its June 2013 meeting. The POC also raised concern at that Board meeting about sever cross-organ issues related to redistricting. The POC then discussed several of these issues at its October 2013 meeting and made recommendations to the Board at its November 2013 meeting. The Board requested more public feedback on the recommendations. In spring 2014 POC contributed to the Liver Committee's concept paper on addressing geographic disparities. The project was then put on hold until comment comes back on the overall liver concept paper and the next steps of the project are identified.

Possible Solutions

Policy Solution

n/a

IT Solution

n/a

Instructional Solution

n/a

Other Solution

While the Liver Committee focuses on redistricting for liver, the POC will focus on the larger issues related to redistricting. Some examples include: 1) should the regions be the same for all organs or certain organs? 2) should the metric of fairness be the same for all organs or certain organs? 3) should the regions be the same for some or all

of the following: organ allocation, Board/committee representation, in-person meetings, and review boards? The POC will develop these recommendations for the organ specific committees to consider as they work on redistricting.

Multi-Organ Allocation

Sponsoring Committee

Policy Oversight

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

There are approximately 500 multi-organ transplants every year that involve organ combinations that are not specifically addressed in policy. (Approximately 850 per year are kidney/pancreas, heart/lung, and liver/intestine which are specifically addressed in policy) The main issue is the allocation of kidneys with other organs when there is a potential for renal function to recover. This impacts the number of kidneys available to candidates with kidney disease. Another area that needs additional clarity is the definition of a multi organ transplant. A third policy development area is to revise the overall multi organ allocation policy.

Progress To Date

There has been a lot of discussion to date. This project has been more defined and POC will take the first step of looking at policies 3.4.F, 3.8, 5.1.B and 5.4.D, 5.8, and 6.4.A to better clarify these existing multi-organ requirements if necessary. 3/2014 - A work group has been formed with members from the Kidney, Pancreas, Liver, and Thoracic Committees and will hold its first call in early April. The Kidney Committee has begun work on a proposal for simultaneous liver-kidney allocation. The Pancreas Committee and the Liver Committee have had an initial meeting to discuss how to define a multi-visceral transplant. Both groups will update the POC on their progress and potential timelines during the April 2014 meeting. At this meeting, the POC will also need to discuss a project plan for any other aspects of multi-organ allocation that needs to be addressed. Of particular note will be the overall multi-organ allocation policy. 7/2014- This project morphed into an overall focus on the general policies without trying to addressing allocation of multi-organs. It focused on cleaning up the existing language so that the organ-specific committees would have solid language to start with when addressing allocation issues.

Possible Solutions

Policy Solution

The committee is considering minimum listing criteria for the various types of multi-organ transplants. This approach would require the most time and could potentially require a significant amount of computer programming. The POC would like to develop a proposed safety net and evaluate its impact on liver-kidney and heart-kidney transplants since those are the most commonly done multi-organ transplants outside of kidney-pancreas, heart-lung, etc. The Pancreas and Liver Committees are working to develop a definition of a multi-visceral and a modified multi-visceral transplant. The POC will lead the effort on revising the overall multi organ allocation policy, particularly starting with these policies: 3.4.F Multi-organ Candidate Registrations If a multi-organ transplant candidate requires a heart, lung, or liver the candidate must register on the waiting list separately for each required organ. Multi-organ candidates who have been named as the recipient of a directed organ donation must appear on at least one of the deceased donor's match runs for at least one of the required organ types. 3.8 Removing Candidates from the Waiting List If a candidate receives a transplant or dies while awaiting a transplant then the registering transplant hospitals must remove the candidate from the hospital's organ waiting lists and notify the OPTN Contractor within 24 hours of the event. If the candidate has multiple-registrations for the same organ, each transplant hospital where the candidate is registered must meet these requirements. The OPTN Contractor will notify other transplant hospitals when a multiple registered candidate receives a transplant or another transplant hospital reports the candidate as deceased. Upon notification, all other transplant hospitals involved can investigate and remove the candidate from the transplant hospital's waiting list. If the transplant recipient re-registers for another organ to replace a transplanted organ, then waiting time will begin as of the date and time the candidate re-qualifies. The

waiting time from the previous registration may be added to the new registration according to Policy 3.6.B: Waiting Time Reinstatement for Non-Function of Transplanted Organ. If the recipient is waiting for a combined kidney-pancreas or kidney-islet transplant and receives only an isolated kidney transplant, the recipient's accrued kidney waiting time will automatically be transferred to the isolated pancreas or islet waiting list. 5.1.B Minimum Acceptance Criteria for Other Transplant Programs All other transplant hospitals may report minimum organ-specific acceptance criteria to the OPTN Contractor, including multi-organ combinations. 5.4.D Multiple Organ Procurement and Offers If an OPO has permission to procure all organs from a deceased donor, that OPO must offer those organs unless, in the OPO's medical judgment, the organs are not suitable for transplant. After the organs have been accepted, all receiving transplant hospitals must agree on when the multiple organ procurement will begin. If they cannot agree on a start time for the procurement, the host OPO may withdraw the offer from the transplant hospitals that accepted the organs. 5.8 Allocation of Multi-Organ Combinations Candidates registered for multiple organs must appear on the heart, lung, or liver match run to be eligible to receive a heart, lung, or liver. When multi-organ candidates other than heart-lung candidates are eligible to receive a heart, lung, or liver, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same DSA where the multi-organ candidate is registered. Heart-lung combinations are allocated according to Policy 6.5.E: Allocation of Heart-Lungs. If the multi-organ candidate is on a waiting list outside the donor's DSA, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type must be paid back to the host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney. If the second organ is a kidney, then the kidney must be paid back according to Policy 8.6.E: Payback Requirements. 6.4.A Waiting Time for Multi-organ Candidates The OPTN Contractor may assign multi-organ candidates waiting time from one waiting list to another waiting list according to Table 6-4 below. Table 6-4: Waiting Time Assignments for Multi-organ Candidates From this registration: To this registration: From this registration: Heart To this registration: Lung Heart Heart-lung Lung Heart Lung Heart-lung Heart-lung Heart

IT Solution

This could require the collection and analysis of additional candidate information as needed for minimum listing criteria. Additionally, there could be changes to the kidney or liver match run. The definitions of multi-visceral transplants would likely require form changes in Tiedi. It is not known yet whether changes to the multi organ allocation policy would require extensive programming.

Instructional Solution

n/a

Other Solution

n/a

Policy Rewrite Parking Lot- Quick Fixes

Sponsoring Committee

Policy Oversight

Public Comment: 2014-September

Board Date: 2015-June

Status Evidence Gathering

Problem Statement

In reorganizing and rewriting the OPTN Policies, it became evident that there were issues that needed to be addressed but would require a substantive change to Policies. These identified issues were placed in the Policy Rewrite Parking Lot. This project will identify and then correct some of the easier items in the parking lot that can be addressed.

Progress To Date

Parking Lot items are sorted by Policy and ready for analysis. 7/15- Proposed changes distributed to committees and UNOS staff for review. 8/1/2014 - POC will vote on proposed policy changes.

Possible Solutions

Policy Solution

The POC will attempt to identify from the long parking lot list, the issues that can be handled easily and are non-controversial. This is likely to include trying to fix ambiguous time frames or time requirements such as "as soon as possible," and "in a timely manner." Other possible quick-fixes include reviewing "shoulds" and either taking them out of policy or making them "musts," making inconsistent terminology consistent, and also looking at the language pointed out by reviewers that has not kept pace with current technology. Once the Committee identifies the possible "quick fixes" we will seek agreement from other Committees as to whether these are indeed non-controversial, simple fixes that can be made.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

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

Sponsoring Committee

Thoracic

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

EVLP technology is emerging, and is likely to help improve otherwise "marginal" lungs prior to transplantation. There is no current policy providing guidance to OPOs for allocating lungs that have been reconditioned. The Thoracic Committee is concerned that without policy, centers that can afford EVLP will monopolize lungs and candidates in farther regions will receive fewer offers. There is also concern that if the technology isn't used appropriately, it could harm a lung that would have otherwise been transplantable. Finally, there is concern that OPOs will not exercise proper precaution when recruiting a lung for transplantation if the lung is going to be reconditioned prior to transplantation anyway.

Progress To Date

4/15/2013 POC Comments and Discussion: Not at this time as the procedure is not FDA approved. The proposal must also look at the timing of reallocation, potential process, cost involved to the center providing the EVLP reconditioning of the lung (supplies, OR time, staff, etc), responsibility of repackaging, etc. Policy as written does not address situation where OPO or 3rd party wishes to purchase and utilize EVLP equipment. While there was some concern about the logistical aspects of this proposal, it was noted that the goal of the proposal is to be prepared for when the technology gets approved by the FDA. July, 2013: During the 2013 ATC, Tom Waddell of Toronto (and the Perfusix group) explained that his company plans on setting up perfusion centers in the US once EVLP is FDA approved. This conflicts with the policy as it is currently drafted. The EVLP Workgroup will meet in August 2013 to address this new development and to continue drafting policy. September, 2013: The EVLP Workgroup reconvened and reviewed the draft proposal, and also reviewed a proposal modeled after recommendations from UNOS. That model will be presented to the Thoracic Committee on 9/26/13. If the Thoracic Committee adopts that model, then it will present the model to the OPO Committee and possibly AOPO to ensure those Committees are also ok with this approach. October, 2013: Members of UNOS staff were invited to Perfusix in Silver Spring, MD to see the building where they plan to establish their first "third party" perfusion center. Perfusix helped explain the status of various FDA trials for EVLP and helped explain their business model. They are aware of the need to be compliant with UNOS policies. November, 2013: The Thoracic Committee adopted the EVLP workgroup's model during the 9/26/13 meeting. UNOS staff has been meeting internally since to determine whether any non-allocation policy changes are required. The main concern (which was also expressed by Dr. Andreoni and Dr. Berg during President's Day) is how do you ensure that the third party perfusion centers comply with OPTN/UNOS policies? There are 2 approaches: 1) treat the third party perfusion centers like any other subcontractor - whoever contracts with them (the transplant center or the OPO) would be responsible for ensuring that the third party perfusion center complies with policies, and if they don't, then the OPO/transplant center is liable; 2) create a membership requirement for third party perfusion centers. UNOS staff is exploring both options. February, 2014: The workgroup met on 1/31 and decided that the issues raised on the call should be presented to POC/Exec for prioritization with other committees' work. (Issues include determining whether EVLP centers should be OPTN members - and that question might only be answered after guidance from HRSA; data reporting requirements while lung is being pumped - for Ops & Safety; requiring reporting of DTAC events either through contract or through policy (depends on whether EVLP centers are members and therefore bound by policy); and guidance for OPOs to determine when perfusion is appropriate; DEQ monitoring plans for OPOs and for transplant programs). March, 2014: The FDA is holding a hearing on 3/20 to determine whether XVIVO perfusion system should be approved. May 1 2014: There is a May 6 Chair call with Carl and MPSC in which they'll discuss the impact of making perfusion centers members rather than allowing them to operate by contract with our members. May 19, 2014 Update: This particular project is going on hold while Membership discusses the membership implications for perfusion service providers. 7/14/14 Update: Membership work group has been formed and will meet soon, though a first meeting date has not yet been chosen. There

still has not been an announcement from the FDA about whether it's approved.

Possible Solutions

Policy Solution

Update as of 9/24/13: Despite the policy drafted by the EVLP Workgroup (copied below), the EVLP Workgroup recently determined it will pursue a different approach; the "Current Allocation" model. The approach adopted would not require any policy change, because lungs would be allocated according to the existing policy. If a center accepts the lung for their candidate, they will be free to pump it if they see fit (either using a pump at their center, or at their OPO, or through a 3rd party provider). Therefore, this approach saves money (no programming changes) time (no need to go out for public comment, no need to wait for implementation) and is also simple and practical. DEQ already monitors allocation, so if the lung ends up transplanted into a candidate for which it was not originally accepted, DEQ will flag that disposition and ask for more information on why that happened. DEQ also assured the group they can provide reports to show how often, if at all, such a practice occurs. The other main concern involved OPO practice – how do you ensure that the OPOs are aggressively and appropriately recruiting lungs, rather than throwing up their hands and deciding to pump every lung. A major factor is cost – it is unlikely the OPOs would pump every lung because such a practice would be cost prohibitive. The OPO members on the Workgroup could not provide a specific explanation for why this practice won't otherwise occur, besides to ensure that most OPOs behave appropriately already, and the bad actors will likely be identified in some way. We will likely need to present this proposal formally to the OPO Committee (after and if the Thoracic Committee adopts it) and also to AOPO. So, rather than making any policy changes, the approach to EVLP will most likely require a very strong educational effort a) to explain to OPOs and centers how EVLP will work in practice once approved by the FDA; and b) to address any concerns head-on from centers or candidates who feel that they don't have "access" to EVLP. March 15, 2013: The Workgroup is drafting a policy to help guide OPOs in allocating lungs that have undergone EVLP. The policy seeks to balance the interest of promoting the new technology, while ensuring that eligible candidates aren't disenfranchised if they are in transplant hospitals without access to EVLP technology. The draft policy as of March 15, 2013 is: A transplant program must obtain informed consent from a candidate prior to registering the candidate as eligible to receive offers of lungs that have undergone reconditioning. An OPO must only allocate a lung for reconditioning if all of the conditions in Subsection 1 or Subsection 2 are met: If the offer originates from an OPO within the 48 contiguous United States and Alaska, All candidates at least through Zone B, as defined by policy 3.7.2, appearing on the match run, have been offered the lung(s) All candidates at least through Zone B, appearing on the match run, have refused the offer All candidates located outside of the contiguous 48 United States, appearing on the match run, have been offered the lung(s) All candidates located outside of the contiguous 48 United States, appearing on the match run, have refused the offer If the offer originates from an OPO located outside the 48 contiguous United States and Alaska: All candidates at least through Zone C, as defined by policy 3.7.2, appearing on the match run, have been offered the lung(s) All candidates at least through Zone C, appearing on the match run, have refused the offer All candidates located outside of the contiguous 48 United States, appearing on the match run, have been offered the lung(s) All candidates located outside of the contiguous 48 United States, appearing on the match run, have refused the offer Upon re-execution of the match run for placement of the lung for reconditioning, the OPO will only offer the donor lung(s) to candidates who have consented to receive reconditioned lungs. After reconditioning the lungs, the transplant center must transplant the lungs into the candidate for which the lungs were designated or release them back to the host OPO, as required by Policy 3.2.4. If, after reconditioning, the transplant center determines the lungs are unsuitable for transplant into the candidate for which the lungs were designated but may be acceptable in another candidate, the Host OPO may offer the lungs to other potential recipients in accordance with Policy 3.7.11.2(b). If the Host OPO offers the lungs after reconditioning, it must provide transplant centers with the following additional information about the lung after it has been reconditioned: Blood gas Change in x-rays over time PA pressures over time Repackaging – who is responsible? Transplant center that reconditioned the lung or Host OPO? OPO. Nothing in this section prohibits a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation.

IT Solution

Programming needed: a new offer rejection code for transplant centers that don't accept on the first pass through the match/a new bypass code for OPOs; a place in Waitlist to indicate consent for EVLP offers; IT solutions for tracking disposition of the organ; might need new data collection fields for lungs while they are on EVLP (though this info may just be able to be attached as a document in DonorNet).

Instructional Solution

n/a

Other Solution

n/a

Collect ECMO Data at Removal for Lung Candidates

Sponsoring Committee

Thoracic

Public Comment:	2014-September
Board Date:	2015-June
Status	Evidence Gathering

Problem Statement

Currently, data for lung candidates supported by ECMO is not collected while the candidates are on the waiting list, and it is not included in the LAS calculation. However, the Lung Subcommittee wants to start collecting ECMO data. In February 2013, the Thoracic Committee advised the thoracic transplant community to report candidates on ECMO as on continuous mechanical ventilation, but it is not possible to distinguish whether a candidate is on ECMO, on continuous mechanical ventilation, or both. ECMO use is additionally collected at the time of registration, and at the time of transplant, but if ECMO use began after registration, or if the patient is not transplanted, ECMO data is not necessarily reported. The type of ECMO is not collected either. As use of ECMO becomes more prevalent, the Committee believes it is critical to collect this data accurately so it can possibly be incorporated in future iterations of the LAS.

Progress To Date

To collect more reliable data, the Lung Subcommittee proposed collecting ECMO data at the time of Waitlist removal, similar to the collection of mechanical circulatory support device information at the time of Waitlist removal for heart candidates. The information collected for heart candidates includes ECMO use, dates of cannulation and decannulation, and all devices ever in place, not just those at time of removal. If similar data is collected for lung candidates, better analysis can be performed regarding the impact of pre-transplant ECMO use on waitlist mortality and post-transplant mortality. The Committee wishes to collect the type of ECMO (VA, VV, unknown), the dates of cannulation and decannulation for each device, and continuous mechanical ventilation with intubation and extubation dates. The Committee suggested phrasing the question regarding mechanical ventilation as “Has the candidate had ventilator support since the time of listing?” The Committee also suggested removing “unknown” as an option under ECMO “Device Type.” The Lung Subcommittee will finalize the list of device types that should be included in the dropdown menu for ECMO, including pumpless vs. non-pumpless, and with or without a ventilator. July, 2013: The Lung Subcommittee decided that the device types to be included in the dropdown are VA and VV ECMO, and mechanical ventilation. They are not going to collect more information than that, for fear of overburdening the coordinators and risking data quality. The Committee learned that this proposal has to go out for public comment because of the Principles of Data Collection adopted by the Board. September, 2013: The Lung Subcommittee presented their proposal to the Thoracic Committee on Aug 1, and the Thoracic Committee requested the Lung Subcommittee collect a little more data. On September 17, the Lung Subcommittee reconsidered the data elements to be collected, and added site of cannulation, and ambulatory vs. non-ambulatory to the form. The proposal is being presented to the Thoracic Committee on 9/26. If the Thoracic Committee approves, the proposal would be ready to go out for public comment in Spring 2014 as long as POC approves the project. November, 2013: The Thoracic Committee voted to approve the Lung Subcommittee's proposal. Staff is currently drafting a public comment proposal scheduled to be distributed for the Spring 2014 cycle. March, 2014: The POC approved the proposal for public comment but the Executive Committee did not. They tabled it until a better, more cost-effective IT solution can be developed. The Committee will continue to try to develop other solutions to collect these important data. April, 2014: Thoracic Committee met in-person in Chicago and re-asserted its desire to pursue this project. May, 2014: IT provided a revised estimate: The revised t-shirt estimate is still very large and we estimate that we can develop the ECMO project for around 2800 hours (about 1000 hours less than the MCS project). July 2014: Thoracic Committee will have a teleconference by early August to vote on the concept of collecting ECMO data - no policy changes are required.

Possible Solutions

Policy Solution

n/a

IT Solution

Modify the Waitlist removal form to collect the ECMO data as specified by the Thoracic Committee. This project impacts the candidate removal page in Waitlist where we will begin capturing and validating these new data. Additionally this project will impact the Tiedi Recipient Feedback Modification form which will allow the Data Quality group the ability to add and modify these data for members.

Instructional Solution

n/a

Other Solution

n/a

Heart-Lung Allocation

Sponsoring Committee

Thoracic

Public Comment: TBD

Board Date: 2014-November

Status Evidence Gathering

Problem Statement

Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) is one of the most confusing policies in all of the OPTN policies. There are several competing interpretations of this policy section and any plain language rewrite of the section would appear to be a substantive change to some members. The policy does not address how to consider geographic classifications when allocating heart-lung blocs off the lung match run. Policy 3.7.7 also does not address how an OPO can "break a tie" between two heart-lung candidates who are eligible to receive the heart-lung bloc.

Progress To Date

The project was put on hold in September 2011. The Committee resumed work on the project in September 2012, assigning it to the Lung Subcommittee. Since then, the Lung Subcommittee has been working on data gathering and examining various solutions to the problem. The Lung Subcommittee drafted a clarification of current policy that will be presented to the Thoracic Committee on March 19, 2013: Current policy: "When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor." Proposed: If the OPO generates the heart or heart-lung match run, the heart will be offered in order of the match. If a heart candidate is eligible to receive the heart offer, but also needs a lung, then that candidate shall be allocated the lung from the same donor. Current policy: "When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart." Proposed: If the OPO generates the lung match run, and the next eligible candidate for the lung offer also needs the heart, the candidate will receive the heart-lung bloc offer unless there is an isolated Status 1A heart candidate in the same geographic zone as the heart-lung candidate. July, 2013: The Lung Subcommittee met and decided the best path forward is to send the clarification explanation to the OPO Committee, to see whether the OPO Committee can decide on a standard way to run the heart-lung match based on the clarification. The OPO Committee may take up this issue at their fall Committee meeting. September, 2013: The OPO Committee met in Sept 2013 and considered the memo sent by the Thoracic Committee explaining the clarification of heart/lung policy and asking for their help. The OPO Committee is developing a heart-lung subcommittee to discuss this problem. February, 2014: The OPO Committee discussed and will send a memo to the Thoracic Committee with details of their decisions. They will draft a way to direct OPOs to consistently allocate heart-lung blocks the same. This definitely seems like a stronger educational effort than previously. Policy still may need to be changed in the future. May 2014- During the April 3 meeting the Thoracic Committee decided to adopt the OPO Committee member's "algorithm" for allocating heart-lungs because it falls within the policy limits. So the first step is to release this document (reformatted) as a guidance document. The next step is to form a Work Group (heart/lung/OPO/Peds) to rewrite policy altogether. There was consensus that the work group should not be formed until after the committee terms renew on July 1, 2014. July 2014 - the Guidance Document will be presented to the Board for approval during its November 2014 meeting.

Possible Solutions

Policy Solution

Change policy to create much more clarity in how to allocate a heart-lung bloc, and to include a provision explaining that the candidates' LAS score will be the tiebreaker in the event that more than one heart-lung candidate is eligible to receive the block.

IT Solution

The clarification of current policy will not require a major IT solution - it may not require any IT solution. However, the Lung Subcommittee may eventually develop a new policy that weighs equity vs. utility, and attempts to equate an LAS with a certain heart Status. If so, it is likely to require major modifications to Waitlist and DonorNet.

Instructional Solution

The policy language clarification will hopefully be clear enough to provide guidance to OPOs when a heart-lung bloc becomes available; however, due to the complexity of the policy it is likely the OPOs will need additional education to demonstrate how to allocate a heart-lung bloc.

Other Solution

During its April 2014 meeting, the Committee determined it would be prudent to take an interim approach, and release a guidance document targeted at OPOs to explain how they should be allocating heart-lung blocks. This guidance document will be based on a model already used by an OPO. The goal is to present this guidance document to the Board in November, 2014 for approval.

Modification of the Heart Allocation System

Sponsoring Committee

Thoracic

Public Comment:	2015-September
Board Date:	2015-November
Status	Evidence Gathering

Problem Statement

The Thoracic Organ Transplantation Committee annually reviews the impact of the heart allocation system since it was modified in July 2006 to prioritize Zone A Status 1A and Status 1B candidates before Local Status 2 candidates. Data reveals that there is a larger percentage of Status 1A candidates awaiting heart transplantation since the modified policy was implemented. There has been an overall decline in waiting list mortality rate, and groups that were intended to be affected the most have experienced the most substantial decline in mortality rate. However, Status 1A candidates are three times more likely to die on the waiting list than candidates in any other status. In addition to the unacceptably high waiting list mortality rate for heart transplant candidates, other problems with the current allocation system include: 1) too many candidates are listed in the most urgent status; 2) there is not enough qualifying criteria for Status 1B; and 3) specific patient populations may be underserved by the current allocation system.

Progress To Date

The Committee has already been reviewing data because they were already doing so in relation to the "Modify 3.7.3 (Adult Candidate Status) to Better Address the Medical Urgency of Candidates Implanted with Mechanical Circulatory Support Devices (MCSD)" project. The Heart Subcommittee weighed the options of modifying the current, 3-tiered allocation system, adding more tiers to the current system, or developing a heart allocation score (HAS). After much discussion, the Heart Subcommittee voted to work on the multi-tiered allocation system because it will be somewhat easier to design and would be more amenable to modification over time. The project initially began because "current policy does not delineate the clinical diversity among candidates implanted with ventricular assist devices (VAD) or MCSDs in general." In 2012, the project description was broadened to include "overall revisions to Policy 3.7.3...because changes to one section of policy could affect another candidate population." June, 2013: The Board approved the release of a guidance document that focuses specifically on Policy 3.7.3, Status 1A(b). It was distributed to heart Regional Review Board members to guide them on approving justification forms submitted as an "other" device complication/infection under Status 1A(b). Though the guidance document isn't binding, it should provide the RRBs with some guidance on the type of infections/malfunctions that are urgent enough to qualify for Status 1A under this criterion. As of September, 2013, the Committee had not received any significant pushback since it was published. July, 2013: The Heart Subcommittee drafted a "straw man" policy that divides heart candidates into six categories based on relative waitlist mortality and post-transplant survival rates. Once the groups in the straw man are completely finalized, SRTR will begin modeling the predicted outcomes using TSAM. Additionally, a forum to discuss items related to heart allocation is in the works, to be hosted by Jon Kobishigawa, in November 2013 in Dallas. The forum might raise additional topics to be addressed during the heart allocation revision. September, 2013: The Heart Subcommittee is still working to finalize the "straw man" categories, and will also need to define the allocation rules before SRTR can run the Straw Man through the TSAM. The Straw Man should be finalized by October 2013. November, 2013: Several staff members and members of the Heart Subcommittee attended the Forum on US Heart Allocation Policy in Dallas. Attendees understood they were not making policy recommendations, but that they were highlighting topics that the Heart Subcommittee should consider before finalizing a heart allocation proposal. Attendees mainly supported the idea of adding tiers to the current system, and agreed that a heart allocation score is impractical for a number of reasons (lack of data, time to implement changes, and the speed at which the field of heart transplantation technology is evolving). The Forum helped highlight certain areas that the Subcommittee should address during policy development, including sensitized candidates, treatment of stable VAD patients vs. patients with VAD complications, inclusions of currently "disenfranchised" candidates, refining the exception process (training for RRBs, creating stricter definitions), and broader geographic sharing. February, 2014: The Heart Subcommittee listened to a presentation by the Histocompatibility Vice Chair regarding CPRA in

the kidney system to see if that experience can help the heart subcommittee with sensitized heart candidates. March, 2014: The Subcommittee reviewed the first analyses performed by SRTR regarding waitlist mortality rates and post-transplant survival rates for candidates when moved into straw man tiers. Additional analyses are being performed and they will evaluate the CPRA data during their March subcommittee meeting. July, 2014: Subcommittee is finalizing allocation rules so that SRTR can model the new tiers.

Possible Solutions

Policy Solution

The Subcommittee is determining how to add additional tiers or stratification to the current three tiered (Status 1A, Status 1B, Status 2) system.

IT Solution

Waitlist will require major modification to include additional statuses and criteria. The new system will also probably require collection of many new data elements, so UNet will need to be modified.

Instructional Solution

Education will be required to teach transplant programs the new stratifications so that they appropriately register their candidates. This likely will be a webinar and definitely will require written materials.

Other Solution

n/a

Pediatric Lung Allocation Policy Review

Sponsoring Committee

Thoracic

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

After addressing the pressing policy issue to determine whether the adolescent classification exception should be permanent, the Subcommittee began to examine the overall fairness of the lung allocation system for pediatric candidates and though they have not identified any explicit problems with the current system, they have identified ways in which the system might be improved. Those solutions are being discussed in ongoing meetings. Additionally, the Subcommittee realized that ABOi transplants could be one part of the solution for improving pediatric lung allocation policy. ABOi transplantation has been a committee project for a few years, but it became evident that the price of programming for the number of candidates that might benefit is too disproportionate. But, if ABOi transplants are part of a larger policy revision, it may still be a potential solution. The Committee was told that one pediatric lung transplant program has started to transplant children who are able to accept a lung from a deceased donor with any blood type (though subsequent attempts to learn the identity of the program were unsuccessful). The pediatric lung allocation policy does not permit allocation of organs to ABO incompatible candidates. The Committee will consider whether or where to place ABO incompatible lung transplant candidates on the lung allocation algorithm. Finally, the recent attention on pediatric lung allocation issues has brought to light the desire to move from the use of specific age brackets in allocation policy toward more clinical criteria (ex. the physical size of the candidate).

Progress To Date

The Committee discussed the project briefly in March 2012, in conjunction with the discussion about pediatric heart transplants for ABO incompatible candidates. Some research for literature on the topic has been completed. During the March 2013 Thoracic Committee meeting, the Committee requested the following data: Number of donors less than 3 year old Number with a lung match run Number with any lung offers made Number with at least 1 lung transplanted Number of lung candidates less than 1 year old Number of lung recipients less than 1 year old Stratify all results by ABO The data is prepared and will be reviewed by the Lung Subcommittee during its October 2013 Lung Subcommittee meeting. November, 2013: Subcommittee reviewed data during October 2013 meeting and realized that there are candidates that would likely benefit from ABOi transplants. The Subcommittee expressed desire to keep policy conservative for now, to only allow candidates less than 1 to receive ABOi transplants. Because data is so sparse because ABOi lung transplants do not occur in the US, and only a few have been performed internationally, the Lung Subcommittee suggested organizing a request for a variance to allow all ped lung transplant programs to perform ABOi transplants for candidates less than 1. February, 2014: The ABOi project is unlikely to go anywhere based on cost/benefit alone, but it may be prudent to roll it into the Ped Lung Allocation Review project because it achieves the same end (prioritizing ped lung candidates in a different way) and would touch the same type of programming. The project title was therefore changed from "Allocation of Lungs to ABO Incompatible Candidates" to "Pediatric Lung Allocation Policy Review" to reflect the proposed broader scope of this policy solution. March, 2014: The Lung Subcommittee continued its discussions and reviewed data - after reviewing data regarding height/size matching, they realized that is not a practical or viable solution and they believe that pursuing broader sharing of adolescent donor lungs may be the correct solution - so SRTR will model that concept for the Lung Subcommittee. As part of this analysis, the Lung Subcommittee will also model broader sharing of adult donor lungs to explore the impact and to determine whether sharing of adult lungs should also be changed in policy. May 2014 - Thoracic Committee asked the SRTR for a TSAM for broader sharing of adolescent and pediatric donor lungs. July 2014 - The Thoracic Committee reviewed the TSAM showing the modeled outcomes of broader sharing of adolescent and pediatric donor lungs, and is debating whether to refine the request.

Possible Solutions

Policy Solution

This policy change would affect Policy 10.4 (Lung Allocation Classifications and Rankings) and possibly other sections as well. Instead of age brackets (ex. candidates less than 12 years old), the policy could use clinical values to allocate organs (ex. size of the candidate).

IT Solution

The IT solution would likely require Waitlist to be modified to indicate a candidate is eligible for ABO incompatible transplants - need a check box, and need to make sure the candidate isn't screened off the match. Waitlist would also need to include more areas for data collection because presumably, the transplant program will have to input data to verify the candidate is eligible for ABO incompatible transplants. The allocation priority of the ABO incompatible candidates is also likely to change. Transitioning away from age brackets could require the collection of different data elements and will certainly require them to be used and programmed differently.

Instructional Solution

Transplant centers would require education regarding the ability to register lung transplant candidates as ABO incompatible, and regarding the candidate's eligibility to be listed as ABO incompatible. Education might only need to be in the form of a memo/guidance doc.

Other Solution

n/a

Proposal to Notify Patients Having an Extended Inactive Status

Sponsoring Committee

Transplant Coordinators

Public Comment: 2014-March

Board Date: 2014-November

Status Post Public Comment

Problem Statement

The goal of this proposal is to promote effective and safe care for organ candidates by increasing awareness of their inactive waiting list status. Published literature suggest that the longer candidates wait for an organ while in an inactive status, the less likely they are to receive a transplant. In addition, the Committee is concerned that candidates are not consistently informed of their status nor do they understand what it means to have an inactive status.

Progress To Date

Multiple committee live meetings have taken place over the past couple of years to review data and discuss how policy should be written. Data have been collected and reviewed that indicate: 1) the greatest percentage of all (active and inactive) registrations as of March 2, 2012, still waiting, had been waiting 1 to less than 2 years; 2) 36% of registrations were waiting in a inactive status; and 3) 66% or more of inactive registrations had been waiting at least 1 year. Draft language for a policy has been drafted and ready for final approval by the committee during their March 2013 meeting. This project has narrowed its focus whereby an immediate education effort will occur following policy implementation and will be limited initially to members. Subsequently, an additional education effort for patients and professionals which will become a separate project including the appropriate tools and resources. August 6 2013, the POC unanimously supported the proposal to go out for public comment to receive feedback for the Committee. Subsequent to that vote, the Executive Committee voted the proposal down thereby preventing the proposal to be released for public comment. Staff worked with the Committee to develop a free process for centers to easily identify their patients having an inactive status and for how long. The Committee is reviewing data to determine the inflection point at which inactive candidates are likely to be long-term inactive candidates. The Committee used this last piece of information to finalize a proposal for spring 2014 public comment. Additional data was reviewed in December 2013 and the TCC agreed that a written notification be sent to candidates at 90 and 365 consecutive days and every year thereafter. The proposed policy language was changed to reflect the earlier notification requirement. This proposal was released for public comment on March 14, 2014. Proposal is currently being presented to committees and at regional meetings for votes and feedback.

Possible Solutions

Policy Solution

3.5.A Patient Notification of an Extended Inactive Status Transplant hospitals must provide written notification to candidates with an inactive waiting list status when the candidate has been inactive for: 90 consecutive days 365 consecutive days Annually, thereafter, for as long as the candidate remains inactive The 90 day written notification must be sent to the candidate within 14 days of the 90th consecutive day of inactivity. The annual written notification must be sent to the candidate within 14 days of their inactive status anniversary date. The notification must include all of the following: The most recent date the candidate became inactive, That the candidate cannot receive organ offers while inactive, and A telephone number at the candidate's transplant hospital to contact for more information Transplant hospitals must maintain a copy of this notification and document in the candidate medical record the date the notification was sent.

IT Solution

The Committee considered a change to UNet under Waitlist Reports. It would add a column or two columns to include candidates having an inactive status and how many days they have been listed with an inactive status. After further discussions, this proposal will not require programming in UNetSM. Transplant Programs will need to have a

process in place to determine when their candidates have been inactively waiting on the waiting list for 90 consecutive days and also for one consecutive year and then notify those candidates. UNOS staff have developed a Microsoft Excel macro that, in conjunction with the “create a custom report” tool in the UNetSM Waitlist application, will help transplant programs with this. The Microsoft Excel macro will allow the user to filter the results provided when creating a custom report in UNetSM and modify them as they see fit. OPTN data requests may initially increase to provide programs with this information until they are able to put processes in place.

Instructional Solution

Professional education will need to be developed to address the new policy language, monitoring and effective practices. Professional resources and tools to educate patients on active vs. inactive may be needed.

Other Solution

n/a

Tiedi Enhancements

Sponsoring Committee

Transplant Coordinators

Public Comment:	N/A
Board Date:	N/A
Status	Evidence Gathering

Problem Statement

There is thought to be enormous variability, in the member community, on how terms are interpreted resulting in varying/inconsistent meanings from center to center when providing data in the Tiedi data collection system. Because these data are used for developing policies, assessing member compliance and assessing member performance, accurate data are critical.

Progress To Date

A TCC working group meets once a month to review fields on the data collection forms. This effort has been ongoing for 16 plus months. It is anticipated that this work will be completed at the end of 2014.

Possible Solutions

Policy Solution

n/a

IT Solution

The remaining data collection forms to be reviewed include the deceased donor registration forms, histocompatibility forms, and post transplant malignancy forms. After these remaining forms are reviewed a report of fields will be forwarded to the subject matter committee for review or to UNOS Professional Development to implement changes in the help documentation. Once the feedback is received from the committees the subcommittee will review the feedback and determine if additional review is warranted to update the field and/or update the online help documentation. A demand request may be needed depending upon the feedback from the other committees.

Instructional Solution

As this project is nearing completion (i.e. all fields have been reviewed), an educational effort will be necessary for those in the community that enter data on these forms to ensure completeness, accuracy and increasing their knowledge of what is specifically being asked.

Other Solution

n/a

VCA database

Sponsoring Committee

Vascularized Composite Allograft

Public Comment: 2015-March

Board Date: 2015-November

Status Evidence Gathering

Problem Statement

Data pertaining to VCA transplantation is needed for future development and refinement of OPTN VCA allocation policy.

Progress To Date

At its 2/25 meeting, the Committee reviewed the OPTN principles of data collection and a general overview of all the data elements currently collected by the OPTN. A Working Group was formed to determine which currently collected data elements are also relevant to VCA, and what other data elements specific to VCA are needed.

Possible Solutions

Policy Solution

Policies regarding data collection for VCA donors and recipients will be modeled after data collection policies for other organs.

IT Solution

This will require new data collection fields in UNet.

Instructional Solution

This proposal will require policy modifications and system changes. While there is a limited number of VCAs programs currently, there is a larger impact due to OPO involvement. This proposal will be monitored for instructional purposes. A small to moderate instructional program will likely be needed prior to the implementation of the database.

Other Solution

n/a

VCA Donor Authorization

Sponsoring Committee

Vascularized Composite Allograft

Public Comment:	2014-September
Board Date:	2014-June
Status	Evidence Gathering

Problem Statement

Members of the public who have formally documented their willingness to be a donor were probably not considering the possibility of vascularized composite allografts. As there is more potential sensitivity about donating VCAs, to sustain public trust, additional and explicit authorization to recover vascularized composites for transplant should be required. Currently OPTN Bylaws and Policies are silent on this matter.

Progress To Date

At its 2/25 meeting, the Committee discussed potential policy language and voted unanimously to send the language it agreed on to the Board of Directors for consideration at their June 2014 meeting. June 24, 2014: The Board approved this proposal (37-0-0). It contained a sunset provision and will go to public comment soon.

Possible Solutions

Policy Solution

Policy stating that authorization to recover vascularized composites for transplant must be explicitly and distinctly obtained from individual(s) responsible for making the donation decision and documented by the Host OPO.

IT Solution

n/a

Instructional Solution

This proposal is currently being monitored for instructional purposes. It may have an impact on members, if any portion policy is modified.

Other Solution

n/a

VCA Membership Requirements

Sponsoring Committee

Vascularized Composite Allograft

Public Comment: 2014-September

Board Date: 2014-June

Status Evidence Gathering

Problem Statement

On July 3, 2014, the OPTN will have oversight over vascularized composite allografts (VCAs). Current OPTN Bylaws do not provide membership requirements for which hospitals may perform vascularized composite transplants.

Progress To Date

At its 2/25 meeting, the Committee discussed potential policy language and voted unanimously to send the language it agreed on to the Board of Directors for consideration at their June 2014 meeting. June 24, 2014: The Board approved this proposal (37-0-0). It contained a sunset provision and will go to public comment soon.

Possible Solutions

Policy Solution

Initial membership requirements will be basic: must be a transplant hospital member and have current approval for at least one designated transplant program.

IT Solution

Modifications to the membership database would be ideal to accommodate formal documentation of VCA programs.

Instructional Solution

This proposal is currently being monitored for instructional purposes. It may have an impact on members, if the bylaws are significantly modified.

Other Solution

n/a

VCA Organ Definition

Sponsoring Committee

Vascularized Composite Allograft

Public Comment: 2014-September

Board Date: 2014-June

Status Evidence Gathering

Problem Statement

OPTN final rule requires the OPTN to list all body parts covered by VCA policies.

Progress To Date

At its 2/25 meeting, the Committee discussed potential policy language and voted unanimously to send the language it agreed on to the Board of Directors for consideration at their June 2014 meeting. June 24, 2014: The Board approved this proposal (37-0-0). It contained a sunset provision and will go to public comment soon.

Possible Solutions

Policy Solution

Include in OPTN Policy the nine criteria added to the OPTN final rule to define a VCA, and list upper extremities and faces as body parts that will have new, specific policies.

IT Solution

n/a

Instructional Solution

This proposal will create additional definitions and modify policy. While there is a limited number of VCAs programs currently, there will be a larger impact due to OPO involvement. This proposal will be monitored for instructional purposes.

Other Solution

n/a