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

Sponsoring Committee

Ad Hoc Disease Transmission Advisory

Public Comment:	2016-January
Board Date:	2016-June
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 - developing failure modes 7/18/14: Conference call scheduled - developing causes and effects related to failure modes 8/1/14: Conference call scheduled -training for the group on rating significance of severity, likelihood, and detectability 8/8/14: Conference call scheduled - continuing to rate and finalize severity, likelihood, and detectability scores 8/13/14: Full Joint Subcommittee met in Chicago for a five hour meeting to develop recommendations to mitigate failure modes, using the scores developed previously to isolate the top 15 failure modes of concern within this communication process. The contractor will use this information to create a finalized report that outlines the outcomes of this FMEA effort. Potential solutions might involve automation of processes, education, policy modifications, etc. Any first steps for policy modifications are anticipated for the January 2015 public comment period. 9/8/14: DTAC leadership met with consultant to determine if there were any additional needs from the joint subcommittee in order to complete final report. 9/12/14: Joint Subcommittee met for its final gathering to complete review of the action plan and discuss next steps. The Committee's BA had discussed suggested DonorNet enhancements with IT leadership. There is internal support for this approach, though it may not be ready for a January 2015 public comment. 9/30/14: The Committee leadership received the final report from the consultant for this effort. 10/30/2014: Based upon unexpected demands related to Ebola impacting many on the Committee, especially the Joint Subcommittee Chair, this effort has been temporarily set aside to focus upon completing another public comment proposal for January 2015. This effort will be held, especially as it is anticipated to include a great deal of programming if not approached in a stepwise fashion. 11/2014: Based upon the Committee members' focus on Ebola and the need to move the "Re-Executing the Match Run" proposal due to its interaction with HOPE Act language, this proposal will be held for August 2015. The Subcommittee Chair (Vice Chair of the Committee) is comfortable with this plan forward. The Committee will continue to work on additional language to address points raised in the FMEA results. 1/9/2015: DTAC is picking this effort back up now that PHS work is nearing completion. The Chair of the Joint Subcommittee worked with internal staff on a potential two-pronged approach to addressing concerns highlighted in the FMEA. The first step will involve addressing policy requirements (proposed Aug 2015 public comment) related to: patient safety contact clarification of what must be

reported by OPOs (system was originally built to consider sick recipients and complete trace backs to confirm or rule out donor as source). Policy in 2.13.A and 15.4 needs to be carefully reviewed and clarified related to OPO reporting expectations. unnecessary reporting leads to desensitization in the community regarding this process, which will leave OPOs and hospitals more at risk for missing when a true transmission event is reported to their patient safety contact- a triaged approach is being explored The second will require programming to automate the patient safety contact list and eliminate the need for some calls to share information (timeline extending into 2016). An email outlining these thoughts was sent to the full committee on 1/23/15 with a request for volunteers from the DTAC to continue this work based upon feedback from the FMEA and experience in the case review process. 1/27/2015: Internal staff from Policy, Member Quality, Regional Administration, Instructional Innovations, and the Organ Center met to discuss the feasibility as well as the pros and cons of automating the center notification process when OPOs post new information to DonorNet. These issues will continue to be explored, but the group was supporting of requesting projected project size for moving the patient safety contact list from its static form as an attachment in the Improving Patient Safety Portal into DonorNet on the on-call tab. This would create functionality for transplant hospitals to change and update this information at will. 2/9/2015: Met with MiYoung and Research staff to bring MiYoung up to speed on this effort and discuss preliminary programming options. She will be collecting information to determine t-shirt size for automating the patient safety contact list as part of an August 2015 public comment proposal. 3/23/2015: Subcommittee call to consider sizing for automating the patient safety contact list and modifications in Policies 2.0 and 4.0 that will clarify reporting requirements for OPOs sharing information with transplant hospitals and reduce reporting to the OPTN for the purposes of DTAC. 3/31/2015: Full Committee received an update on the effort and shared thoughts regarding streamlining of the reporting process to reduce unnecessary reporting of positive cultures without sick recipients by OPOs. 5/29/2015: Subcommittee met to review draft language and discuss streamlining ideas. Two more calls in June planned to finalize language for August public comment.

Possible Solutions

Policy Solution

The joint DTAC-OPO-TAC-TCC 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

Staff is currently reviewing the expenses related to automating the patient safety contact list to allow members to update the list in real time. This information is expected in May 2015.

Instructional Solution

This proposal will require a instructional program and will be monitored for specific needs throughout the development and implementation to determine the best course of action for instructional delivery.

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.

Define "Exhausting the Match Run"

Sponsoring Committee

Ad Hoc International Relations

Public Comment:	TBD
Board Date:	TBD
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. However the policy does state "after offering these organs to all potential recipients on the match run." 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. There are an average of 43 organs exported to foreign countries each year, with 80% of those exported having documented offers to the end of the match run. (87% of exported organs are hearts and lungs)

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). 2/3/2014 - The Joint Subcommittee convened on to discuss the issue. During the rewrite of the previous OPTN Policy 6, one of the issues raised was how many offers an OPO must make prior to exporting an organ outside of the U.S. Historically, exported organs were only sent to Canada. Typically, the majority of those were thoracic organs where cold ischemic time greatly impacted the time available to avoid organ wastage. 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. 4/22/2014 - The data request was fulfilled and reviewed by the IRC import subcommittee group. 7/21/2014 - The data was re-reviewed by the IRC leadership team with a suggestion for clarification of the reasons why import matches were excluded from the analysis. Additional granularity of data was also requested on the deceased donor liver and kidneys offered nationally and exported to include the age and reason that the match run was not exhausted in these cases and the organs were subsequently offered outside of the US. Refusal information was also requested for these organs. The purpose of requesting the additional detail is to review the confounding factors which may trigger organ exportation. It was suggested that other committees may be examining refusal data and options for presenting the data could be investigated for replication to the IRC import group. The IRC export subcommittee will reconvene to review the data and discuss options once the revised data request is fulfilled. No recent progress due to liaison change and workload.

Possible Solutions

Policy Solution

Following review of the data and joint subcommittee discussion, 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 specific instructional needs throughout development and implementation to determine the best course of action for instructional delivery.

Other Solution

n/a

Ethical Considerations of Imminent Death Donation

Sponsoring Committee

Ethics

Public Comment:	N/A
Board Date:	2015-December
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

4/2013: Briefly discussed during full Committee meeting, and Dr. Morrisey participated and presented by web conference. 4/2013 - Ethics Committee Chair presented this topic to the Living Donor Committee by web conference. 10/2013- 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. 3/2014 - The Ethics Committee discussed IDD during it full Committee meeting and heard presentation Drs. Morrisey 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 6/2014- The Executive Committee of the Board approved this project. 7/2014 - 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. 8/2014 - The workgroup held its first call, and some members of the workgroup did not support IDD under any circumstances. Workgroup members we asked to consult their committee to gauge their opinions on IDD. The workgroup is planning to meet again in late September. IDD workgroup was scheduled to meet in December but the meeting was cancelled at last minute due to sudden conflict with Chair's schedule. IDD workgroup rescheduled to meet on 1/14/15 1/2014: IDD workgroup met identified a list of issues that would need to be addressed before and educational resource or potential policy requirements could be developed. The work group plans to meet again in February 3/2014 - IDD workgroup met. Current plan is to develop a report for all Committees represented on the workgroup to consider at their spring 2015 meetings, and to provide the report to the Board in June 2015. The Board could be asked to determine if IDD policy development should proceed. 5/2014 - Completed report identifying all issues with IDD that would need to be addressed. IDD remains controversial and because there is a lack of consensus regarding if IDD would ever be appropriate it may be necessary for the Board to determine if this project should be pursued.

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. This proposal will be monitored throughout the development and implementation to determine the best course of action for instructional delivery.

Other Solution

The Ethic 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 and discussed this potential new project and discussed possible approaches for reviewing the proposals. The Committee formed three workgroup with each workgroup assigned to review a subset of the white papers, and determine if each paper should be maintained, revised or eliminated. Some white papers should be ready for reconsideration by the BOD in June 2015 Workgroups have established a plan for each white paper. Approximately 1/3 of the white papers do not require modification, 1/3 need minor modifications and 1/3 need major modification. The Board approved a revised white paper addressing the allocation of human organs during its June 2015 meeting. Other white papers should be ready for consideration by the OPTN/UNOS Board in December 2015.

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.

Annual Update to Equivalency Tables (2015)

Sponsoring Committee

Histocompatibility

Public Comment:	2015-August
Board Date:	2015-December
Status	Evidence Gathering

Problem Statement

Pursuant to Policy 4.7, the Histocompatibility Committee must review and recommend any changes need to the equivalency tables on or before June 1 of each year.

Progress To Date

02/19/2015: The HLA Equivalency Table Subcommittee meet for the first time in 2015 to discuss updating the equivalency tables. This annual update will also include the addition of DQA and DPB to the equivalencies. These two antigens were approved by the Board of Directors in November 2015. Additionally, the Committee decided to pursue an educational effort to ensure that laboratories are aware of the upcoming changes. The Committee determined this educational effort should include writing an article describing how to interpret the equivalency tables and new modifications. 03/03/2015: The HLA Equivalency Table Subcommittee continued discussion on what modifications to make to the tables. In particular, subcommittee members submitted draft copies of the policy with recommendations. 03/23/2015: The HLA Equivalency Table Subcommittee held a conference call to walk through the various recommendations. The Subcommittee Reviewed the proposed modifications from members and ended their review at Table 4-5 HLA DR Matching Antigen Equivalence. 6/17/2015: The full Committee met and approved sending the proposal out for public comment for the Fall, 2015 public comment cycle.

Possible Solutions

Policy Solution

n/a

IT Solution

This year's updates includes changes that will drive a different method of data collection, cpra calculation and screening related DR51, DR52, DR53

Instructional Solution

n/a

Other Solution

n/a

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

Sponsoring Committee

Histocompatibility

Public Comment:	2016-August
Board Date:	2016-December
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

6/04/15: Survey was sent out to transplant programs and histo labs 5/20/15: The committee approved final survey language and requested analysis of survey results (once the survey is completed) 6/04/15: Survey was sent out to transplant programs and histo labs 5/20/15: The committee approved final survey language and requested analysis of survey results (once the survey is completed) 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. 09/03/14: During the Committee's Aug. 11-12, 2014 in person meeting, a series of draft survey questions were presented to the Committee for feedback. Data was presented to the Committee on the CPRA distribution of kidney registrations on the waiting list for different demographic groups. The intent was to see whether this proposal has the potential to advantage some of the minority and demographic groups. The data was used to reinforce which groups are highly sensitized. SRTR presented KAS simulation modeling designed to address at what CPRA level sensitized candidates become disadvantaged in the new KAS. 11/20/14: The KAS Desensitization Workgroup met on 11/05/14 to continue discussion on CPRA prioritization points for kidney candidates undergoing desensitization. The Workgroup reviewed KAS simulation modeling: looking at transplant rates, at what level (based on CPRA) do sensitized candidates become disadvantaged in the new KAS? The Workgroup also reviewed data previously presented to the Histocompatibility Committee on the CPRA distribution of kidney registrations on the waiting list, overall for different demographic groups. The Workgroup continues to construct a survey for eventual distribution. Recommendations and suggestions from this call will be incorporated into a revised survey for presentation at the Workgroup's next call. 12/09/14: Pursuant to the last call, clarifying questions were added to the survey. After the survey is vetted through the Workgroup it will be presented before the Histocompatibility Committee. The ultimate goal of the call was to approve the survey for submission to the represented committees (Histocompatibility, Kidney, and Minority Affairs). 01/12/2015: The Histocompatibility Committee held a conference call on December 17, 2014 to review the KAS Desensitization Survey and provided recommendations to the KAS Desensitization Workgroup. During the course of discussion, members made recommendations and suggestions which were incorporated into the survey. 02/12/2015: Internal survey team completed review of KAS Desensitization Survey. Survey was emailed to committee chair for final feedback. 04/21/2014: Survey questions configured using survey monkey. Survey pending internal review. 05/18/2015: Project placed on "hold" due to IT implementation and OPTN Strategic Goal alignment. Will communicate to leadership during Leadership Call 05/19. Cancelled duplicate project form

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

This proposal may require an instructional program and will be monitored for specific needs throughout the development and implementation to determine the appropriate modality for educating members.

Other Solution

n/a

Histocompatibility Testing Guidance Document

Sponsoring Committee

Histocompatibility

Public Comment:	N/A
Board Date:	2015-December
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

June 2014: The Board of Directors approved the histocompatibility policy rewrite. This project is being marked as an ongoing 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 Cytoxicity 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 08/2014: The Committee decided to create a subcommittee to bring a proposal forward to the full committee to determine how much granularity there needs to be in the guidance document. 11/20/2014: On October 15, 2014, the Guidance Document Subcommittee held its first conference call. The Subcommittee reviewed a crosswalk created during the policy rewrite that outlined various sections for incorporation into a guidance document. The Subcommittee decided it best to review the sections holistically and then at a later date specifically address each section in more detail. The Subcommittee is about halfway through a first review of the guidance document sections. 01/09/2015: The Guidance Document Subcommittee met via conference call on December 1, 2014. The subcommittee is reviewing a draft version of the guidance document. 03/25/2015: Vice Chair Submitted first draft of guidance document.

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.

Kidney Allocation System (KAS) Clarifications and Clean Up

Sponsoring Committee

Kidney

Public Comment:	2016-January
Board Date:	2016-June
Status	Evidence Gathering

Problem Statement

The revised kidney allocation system (KAS) was implemented on December 4, 2014. Since the policy was approved in June 2013, the Kidney Committee and UNOS staff have identified a number of clarifications that are needed in the policy language (see Proposed Solutions). The Kidney Committee believes it is important for the OPTN to address these clarifications in order to ensure maximum efficiency in the revised KAS.

Progress To Date

12/14: The Committee staff discussed this project with the Committee leadership and determined that this is a very high priority for the Committee. If approved, the KAS Implementation Subcommittee will begin work on this project in January 2015. Subcommittee calls have been scheduled for January, February, March, and June. 01/08/15: The POC reviewed the request for the project and recommended approval. There was a substantial discussion, however, about the need to clarify the order of allocation and OPO authority and responsibilities in cases where the kidney is shipped for a high CPRA candidate but the intended recipient cannot be transplanted. The POC would like an update in March about what the Committee has recommended on several of the identified issues. Agendas have been set for the January and February calls. On the January call, the Committee will review the first 'out of the gate' numbers on the new kidney allocation system and the data monitoring plan that was submitted to the Board in June 2013. On the February call, the Committee will discuss the first round of policy tweaks that have been identified as referenced in the Proposed Solution section. 03/15: The subcommittee has been meeting monthly January-March. The group has reviewed the early, out-of-the gate data reports. Although the Committee has heard anecdotal reports of inefficiencies in the shipping process (most specifically dealing with shipping blood in advance of kidneys and transplant programs not performing crossmatches early enough), the subcommittee does not feel that the data warrants any policy changes at this time. The Committee is working with the OPO Committee to consider whether some official OPTN guidance on best practices for shipping may be needed. The Committee has discussed some of the policy issues outlined below, but the discussion indicated that many of the issues are much more substantive and complex than staff originally thought. So, staff have moved out a longer timeline for the first phase of this project. 04/15: At the in-person meeting, the committee reviewed the 'out of the gate' data and agreed with the implementation subcommittee that nothing in the data suggests any major changes are needed immediately. However, the committee would like to continue to discuss some of the logistical shipping issues with the OPO Committee and consider whether a requirement is needed to ensure that the blood sample is shipped early in the process. The implementation subcommittee will discuss this and other possible policy changes going forward. 05/15: Darren has informed UNOS and committee leadership that KAS data suggests that the discard rate is increasing post-KAS. UNOS research is trying to identify the reason for the increase.

Possible Solutions

Policy Solution

Some of the tweaks that have been identified thus far that the KAS implementation subcommittee will need to discuss: Policy 8.2.B Deceased Donor Kidneys with Discrepant HLA Typings This policy says that a kidney with a discrepant HLA typing can be allocated according to the original HLA typing or the recipient transplant hospital may reallocate the kidney locally. UNOS staff flagged this section because it is unclear whether there are patient safety issues associated with allocating a kidney based on the wrong HLA data. In addition, this section may be in conflict with 5.7 Release of Organs which says that the host OPO has the authority to decide whether to allocate a kidney based on its own match or allow the importing OPO to do so in the event that a kidney cannot be transplanted into

the original recipient. The Committee will need to decide how to clarify how allocation will work in this instance. Policy 8.5.G Highly Sensitized Candidates This policy says that the HLA laboratory director and the candidate's physician or surgeon must sign a written approval of the unacceptable antigens for candidates with a CPRA greater than 98% to receive regional and national sharing priority. UNOS staff received feedback during the education phase of KAS (mostly from transplant administrators) that the lab director and physician/surgeon need to be able to designate someone to provide the written approval. There are many cases where the HLA laboratory director serves several different labs and is not physically located close to the transplant program. In the KPD histocompatibility policy, the Kidney Committee addressed this concern, allowing for a designee to be selected for either the laboratory director or the physician or surgeon. The Committee will need to decide whether it is appropriate to allow a designee to provide written approval for regional and national allocation eligibility. One additional cleanup is needed in this section: the policy language only references Table 8-6 (allocation sequence B) for regional and national priority for these candidates but it needs to reference all allocation sequences (i.e. Table 8-5, 8-6, 8-7, and 8-8). Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85% This policy described the candidate order for allocation. During the programming phase of KAS, IT staff reported that there is some duplication of classifications, so that no candidate would fall in a lower category because they are already described in an above category. One example deals with a description of candidates with a blood type identical or permissible to the donor in classifications 13 and 23. There have been a couple of these identified in the other classification tables as well. Table 8-9 Organ Offer Limit This policy outlines the number of mandatory share offers an OPO must make within a specified period of time. This policy was converted from the previous kidney policy when the Board considered it. After discussions with organ center and regional administration staff, it is clear that the policy is meant to convey more than it currently outlines. OPOs use this policy to make a minimum number of mandatory share offers and, once that number is reached, they use a bypass code to begin making local offers. UNOS staff would like to discuss this policy with the Committee and determine whether this is still the intent of this policy and provide clarifying language that will make requirements clearer to OPOs. Policy 8.7.C National Kidney Offers This policy describes instances when the Organ Center will handle placement of national offers and makes clear that OPOs still handle zero antigen mismatch offers and those regional and national offers to candidates with CPRA greater than 98%. The second paragraph references the "importing OPO" as allocating a kidney that was accepted but not transplanted and this appears to conflict with 5.7 Release of Organs which says that the host OPO has this authority. 8.7.D Kidney-Non-renal Organs Allocated and Not Transplanted: This policy says that if the kidney was allocated as part of a multi-organ combination offer but could not be transplanted, it must immediately be offered for zero antigen mismatched candidates. However, in highly sensitized candidates (greater than 98% CPRA) now come before the traditional zero HLA mismatch offers in the match sequence. The language needs to require that the kidney be allocated using the kidney-alone classifications in Policy 8.

IT Solution

There will be IT efforts associated with any changes made to the classification tables (see example in description of possible changes to 8-8 in Proposed Solutions above). In addition, there have been a number of 'nice to have' programming clean ups identified by the Committee and UNOS staff. Those may be incorporated into this policy clean up effort as well.

Instructional Solution

There will likely be a small educational effort to make the community aware of these clarifications. It is likely that educational efforts will be focused around communication on the OPTN website, TransplantPro website, and the Transplant Administrators and OPO listserves. This proposal will be monitored for specific needs throughout the development and implementation to determine the appropriate educational modality for members.

Other Solution

n/a

Simultaneous Liver Kidney Allocation

Sponsoring Committee

Kidney

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

Problem Statement

The OPTN Final Rule specifies that organ allocation policies must be based on sound medical judgment, contain standardized criteria for allocating each organ type and combination of organ types, and must seek to achieve the best use of organs, avoid wasting organs and futile transplants, and promote efficient management of organ placement. There are minimal rules for SLK allocation. When a liver-kidney candidate and the donor are in the same DSA, OPTN policy specifies that the kidney must be allocated with the liver. However, there are no standardized medical criteria that allocation is based on. When a liver-kidney candidate and the donor are in different DSA's, there are no policies defining rules for how the organs will be allocated. The OPO can opt to allocate the kidney with the liver or to allocate both organs separately. The policy does not provide for a consistent set of allocation rules that is based on patient need. The lack of consistent local and non-local allocation rules for SLK is counter to these Final Rule principles.

Progress To Date

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 nehrosclerosis, 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 nehrosclerosis, 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><35 in the new allocation system), SLK transplants in which the kidney was not needed may disproportionately affect pediatric access to kidneys. • On average, 200 patients were listed per year for a kidney transplant during 1/1/05-6/30/13 after a solitary liver transplant; the median time to listing for these patients was about 9 years for those with a kidney diagnosis of CNI nephrotoxicity, 6.5 years for hypertensive nephrosclerosis, 5 years for type 2 diabetes, and 11 months for hepatorenal syndrome; additionally, only 19% were listed within a year of the liver transplant. • On average, there were 120 kidney transplants (including both deceased and living donor) performed per year during 1/1/05-6/30/13 after a solitary liver transplant; the median time to kidney transplant was 10 years for those with a kidney diagnosis of CNI nephrotoxicity, 7 years for hypertensive

nephrosclerosis, 6 years for type 2 diabetes, and 2 years for hepatorenal syndrome; additionally, only 9% were transplanted within a year of the liver transplant. • The 25th percentile of times to deceased donor kidney transplant tended to be lower for registrations added to the waiting list during 2003-2008 after a previous liver transplant as compared to those added to the waiting list during the same time period without a previous liver transplant. April 16, 2014: POC received an update on this project. Below are comments/recap of the discussion. Several members argued that multi-organ transplant outcomes should be included in PSRs. Jon Snyder from SRTR commented that HRSA is supportive of including these in PSRs and they are looking at a phased approach for including them (part of the phased approach will mean that the MPSC will need to decide whether or not they want to look at these as part of outcomes review). The Committee had a discussion about whether it is ethical to give liver alone transplant recipients additional priority for kidneys after their liver transplant (the 'safety net'), while other candidates waiting for a kidney alone transplant have been on dialysis for significant periods of time. Peter Reese (Ethics Committee, will be on SLK workgroup) commented that there are several ethical issues at play with this issue. The Ethics Committee probably wouldn't be opposed to a safety net proposal, because there is an argument that patients who have multi-organ failure are worse off than other patients who need one organ. There is also a fairness issue in that some programs are more willing to do SLK transplants than other programs who have patients equally as sick who do not accept the dual organ offer. Dr. McCauley (MAC, will be on SLK workgroup) commented that 'worse off' should be based on outcomes data.
Several members of the Committee commented that the Committee needed to determine the purpose of the safety net and whether this solution would mitigate the number of SLK transplants for patients who may regain kidney function or decrease the number of SLK transplants in general (because those patients who would truly need the kidney will likely be too sick to get back on the list and, therefore, it may not be a true safety net).

July 14, 2014: Monthly conference calls have been scheduled for the SLK Workgroup. The first call will take place on August 18, 2014.

August 18, 2014: The workgroup held an introductory call. The purpose of the call was to present the background on the project and have the workgroup discuss and come to consensus on a problem statement.

Problem Statement
The Kidney Committee had previously submitted a problem statement for the workgroup to consider:

Data suggests that a portion of kidneys are allocated to liver candidates who likely would have regained their kidney function following a liver alone transplant. Recent data show almost half of SLK recipients received a kidney with a KDPI less than 35% (a category of kidneys that is prioritized highly for pediatric candidates). The lack of allocation rules is counter to Final Rule principles regarding the best use of organs and allocation policies being based on medical urgency.

Some of the workgroup members did not agree with the first part of this problem statement, asserting that the data doesn't show who is likely to regain kidney function after a liver transplant. The majority of the workgroup agreed with this and that portion of the problem statement was removed. There was also some questions about whether there has been a reduction in access to kidneys for pediatric patients because of the mandatory sharing rules around local SLK allocation and how that issue was related to the problem. Since the KDPI data was related to this element of the problem, that portion was also removed from the problem statement. The workgroup did agree that there should be more well defined rules around SLK allocation and that the lack of rules and consistency is counter to the Final Rule principles of regarding policies being based on medical criteria and medical urgency. The Committee agreed on the following amended problem statement: There are minimal rules for SLK allocation. There is a need for more consistency for these transplants, especially when a liver is being shared (non-local). The lack of allocation rules is counter to Final Rule principles regarding the best use of organs and allocation policies being based on medical urgency. There was some discussion about whether the issue of broader sharing of liver/kidneys is out of scope for this workgroup and whether the OPO representatives had specific feedback on that piece of the problem statement. One of the OPO representatives offered that it would be a positive step to have consistent practice for OPOs on allocation of SLKs. 2009 proposal Several members indicated support for the overall elements of the 2009 proposal (creating both listing criteria and a safety net for liver recipients with

continued kidney failure). Some members expressed concern over the current policy regarding voluntary sharing of the kidney (with the liver) if the donor is non-local, advocating that sharing should be consistent in these instances (not a decision that belongs with the OPO). Several members of the Liver Committee expressed concern that the number of SLKs have decreased since the introduction of the Share 35 proposal, and this may mean that patients who need an SLK have reduced access due to the voluntary sharing policy. Supporting Evidence The majority of the workgroup agreed that additional data is not likely to help in determining what patients are more likely to regain kidney function after liver transplant. Because of the lack of data, it may be difficult to develop an allocation policy around listing criteria that is based on hard evidence. Members did discuss wanting to focus on the outcomes of these transplants--both patient survival and kidney graft survival. The workgroup chair agreed to circulate some recent publications related to SLK outcomes and waiting times v. number of transplants performed by DSA (with particular focus on impact to pediatric population). These were data points that members of the workgroup seemed interested in reviewing together in the future. Ethical Considerations Some of the workgroup members discussed recent feedback from the POC regarding ethical considerations of the issue. One issue that was discussed in particular was whether it was fair to prioritize a liver recipient on the kidney list when they would be given the same (or more) priority than a kidney candidate who had been on dialysis for many years. The members agreed that this issue will require them to balance fairness and utility and it will be difficult to balance the survival of liver candidates v. survival of kidney candidates. Considerations for Specific Patient Populations A member of the workgroup from the MAC did want to see any available data on how the current SLK policy may have some effect on access to kidneys for pediatric candidates. There was also mention of considering sensitized patients who may benefit from having only one donor. September 22, 2014: The work group reviewed the summary of the data previously presented to the Kidney Committee along with highlights of several articles published on the topic. The Work Group members discussed the data and agreed that kidney graft outcomes, recipient outcomes (patient survival) as well as waiting list mortality data for different groups of patients need to be taken into account when making recommendations on policy changes. These data will address the following research hypotheses: For each group of patients, what is survival advantage of receiving a kidney vs. remaining on the waiting list? Between different groups of patients, what is the difference in outcomes? What are kidney graft survival rates for multi-organ recipients (SLK, heart-kidney) compared to kidney alone recipients? October 2014: The workgroup finalized recommendations for eligibility criteria (minimal tweaks were made to the criteria proposed in 2009 public comment proposal): In order to be eligible to receive a kidney along with the liver from the same donor, the liver candidate must meet one of the following kidney criteria: Chronic renal failure Candidate has begun dialysis for ESRD; or Candidate has eGFR less than or equal to 35 mil/min Sustained acute renal failure Dialysis for six consecutive weeks or more; or eGFR less than or equal to 25 mil/min (confirmed every 7 days in the medical record) for six consecutive weeks; or Any combination of above two bullets for a total of six consecutive weeks Metabolic disease Diagnosis of hyperoxaluria, atypical HUS from mutations in factor H (and possibly factor I), familial non neuropathic systemic amyloid, or methylmalonic aciduria Note: methylmalonic aciduria was added at the request of the chair of the Pediatric Committee. November 2014: The working group discussed and finalized details about the safety net. The following are the details of the safety net: If, 2-12 months after their liver transplant, a candidate has either 1)begun dialysis for ESRD or 2)has an eGFR at or below 20 mil/min), then the candidate will receive additional priority on the kidney waiting list through the candidate classification scheme. The working group recommends that this apply to all prior liver recipients regardless of whether they met the criteria before their liver transplant. Once they meet the criteria in this time period, they will continue to be eligible for the additional priority. The classification priority looks different based on the donor KDPI. Because there was and has been significant concern from the kidney transplant community about access for highly sensitized and pediatric kidney candidates and also for better utilization of kidneys through longevity matching, we are recommending that we prioritize liver recipients on the kidney waiting list in the following way: In sequence A (KPDI equal to or less than 20%), there would be no prioritization assigned for these candidates (please note that these candidates could still fall into sequence A if they met one of the other classifications). In sequence B (KDPI between 21-35%), these candidates would be prioritized after pediatric candidates, since kidneys with KDPI less than 35% are typically prioritized for this population. In sequence C (KDPI between 36-85%), these candidates would be prioritized after prior living donors. In sequence D (KDPI between 86-100%), these candidates will be prioritized after zero mismatch offers. It's important to note that the majority of all kidneys are allocated within sequence B and C. All prioritization would be limited to the local DSA. December 2014: The working group reviewed draft policy language for the eligibility criteria and discussed next steps for getting feedback from the regions, professional transplant societies, and

other committees and groups. January 8, 2015: The POC discussed multi-organ issues on their full committee conference call. The POC requests that the SLK project be broadened to discuss and resolve a host of multi-organ policy conflicts. UNOS staff is discussing this possibility with the working group chair and policy department leadership. January 12, 2015: The working group reviewed the results of the September 2014 data request. In summary, the data concluded: There seems to be a survival advantage of receiving a kidney along with a liver over receiving a liver alone, but only for those candidates experiencing renal failure. For both groups of SLK recipients with and without renal failure had significantly lower kidney graft survival rates within several years post-transplant, which was primarily driven by the high mortality rates, especially within the first three months of transplant. Also, for the kidney after liver transplants, waitlist mortality was higher than compared to the kidney alone, but the post-transplant survival seemed to be very similar to the group of patients without previous liver transplants. The group concluded that the data provides some justification for the medical eligibility criteria as well as the safety net prioritization. January 26, 2015: The Kidney and Liver Committees reviewed and discussed the working group recommendations. Both committees provided full endorsement of the recommendations. Next steps: The recommendations will be presented at the regional meetings and other committees in February and March. The Kidney Committee has begun outreach to NKF, AUA, AST, ASTS, NATCO, and AOPO. February 16, 2015: The working group finalized draft policy language for the safety net and discuss whether it is appropriate to apply to thoracic/kidney combinations as well. April 13, 2015: At the Chicago in-person meeting, the Kidney Committee approved an SLK policy to be released for public comment in August. The Committee made one change from the working group recommendations—making it clear that the safety net priority will only apply for SLK recipients if they experience kidney graft failure within the first 90 days of their SLK transplant. UNOS staff will begin writing the background/history and explanation for the public comment document. June 2, 2015: The Committee presented the draft recommendations to the OPTN/UNOS Board of Directors for feedback and asked for direction on the following items: Whether the medical eligibility criteria and safety net application are appropriate Whether SLK allocation should be expanded to the regional level of distribution Whether the Committee should wait until the other larger multi-organ order of allocation issues are worked out before bringing a final policy back to the Board for approval. The feedback from the Board was positive. Several members encouraged the Committee to bring the proposal back before the Board in the next year, and they were comfortable with this being the case even though there may still be issues to work out with multi-organ allocation. There was also overwhelming support for allocation of kidneys with livers on the regional level for those liver candidates with MELD greater than 35. June 15, 2015: In response to the direction provided by the Board, the Committee decided to tweak the policy language recommended for public comment. The updated proposal now specifies that a candidate who meets the SLK medical eligibility criteria will be eligible for both local and regional SLK allocation if the candidate is eligible for Share 35 priority under the liver allocation policy. The Committee unanimously agreed to this

Possible Solutions

Policy Solution

The policy proposal includes: changes on the liver waiting list to create medical criteria to determine eligibility for receiving a kidney with a liver from the same donor changes to kidney allocation policy to create a new match classification in kidney allocation for liver recipients on the kidney waiting list with post-operative dialysis dependence or significant kidney dysfunction

IT Solution

This proposal may require changes to the kidney and liver allocation systems.

Instructional Solution

n/a

Other Solution

n/a

Define "Biologically Incompatible" for KPD

Sponsoring Committee

Kidney Paired Donation

Public Comment:	2016-January
Board Date:	2016-June
Status	Evidence Gathering

Problem Statement

There is currently no policy or bylaw limiting entrance into the KPDPP to incompatible pairs. However, while NOTA defines KPD as an option for incompatible pairs, it does not define biologically incompatible. This has caused confusion regarding which living donor pairs are eligible for paired donation.

Progress To Date

March 13, 2014: This idea came to light during Dr. Ratner's presentation at UNOS. It was discussed briefly at a KPD staff meeting. The idea seems promising as it could bring more participants into KPD, which creates a promise for more matches. The idea will be presented to the KPD Workgroup yet. April 14, 2014: Staff researched NOTA, which specifically describes paired donation as "incompatible." September 22, 2014: KPD Staff met with UNOS General Counsel to discuss whether compatible pairs may enter the OPTN/UNOS KPDPP without violating the Charlie Norwood Act. Counsel noted that the Charlie Norwood Act was not controversial when passed, so there is very little by way of legislative history to let us know the intent of the law (which describes KPD as a donor being "biologically incompatible" with the intended recipient). Counsel recommended that the KPD Work Group (and Kidney Committee) define "biologically incompatible" in policy, because then we will be taking a transparent path forward with room for public comment. October 6, 2014: UNOS Staff spoke with KPD Work Group and Kidney Committee leadership and agreed that this project is a priority for the KPD Work Group and decided it should be submitted to the POC for consideration as a new project at the end of October. October 20, 2014: The POC met to review requests to work on new projects. The POC approved this project so the KPD Work Group can begin working on it. However, POC advised the Work Group to further refine the problem statement so that it is very clear why this project is necessary. November 12, 2014: The Executive Committee approved the POC's recommendations to permit the KPD Work Group to work on this project. November 18, 2014: The KPD Work Group met to discuss project planning. Members of the work group are dividing themselves between working on this project and working on revising the KPD priority points. Dr. Cliff Miles agreed to lead the group addressing this topic. January 2015: UNOS Staff began work to schedule a monthly meeting of a subgroup of KPD Work Group members to work on this project. February 16, 2015: A small group of the KPD Work Group met to begin discussing the biologically incompatible definition. They drafted a proposed definition and UNOS staff is working internally to clean up the draft and schedule a follow up meeting. The group agreed that the definition should be as flexible as possible within the bounds of NOTA. March 17, 2015: The Subgroup met to revise the definition developed on the last call. The Subgroup will vote on a final definition on the next call. April 13, 2015: The potential definition was presented as a part of the KPD Work Group update at the in-person Kidney Committee meeting in Chicago. Committee members indicated that they would like for the definition to also include kidney function, hypertension/physiology, and disease transmission (including cancer) to the list of categories that a pair could be considered incompatible. April 14, 2015: The JSWG met to review new OPTN projects and decided to pass on defining biologically incompatible. April 21, 2015: We presented the progress on biologically incompatible to the KPD Work Group for initial feedback. Work group members did not have any additional suggestions after the presentation. April 29, 2015: The subgroup met to finalize the definition taking into account Kidney Committee feedback. The subgroup voted to add histology, microbiology, and physiology based on Kidney Committee feedback. The final definition: The transplant physician or transplant surgeon may determine that a donor and a candidate are biologically incompatible based on clinical characteristics including one or more of the following: Age Anatomy Blood type Body size Gender Histology Immunology Microbiology Physiology Serology The subgroup began discussing whether they want this definition to be monitorable, but did not come to any final decisions. Future discussion is needed. June 12, 2015: A memo was distributed to NATCO, AST, ASTS, NKR, APD, and a few same center programs asking for feedback on the subgroup's draft definition. Responses were

requested by July 15, 2015.

Possible Solutions

Policy Solution

The policy change will require a modification to the current definitions. OPTN Policy defines KPD in the same way that NOTA does - as "biologically incompatible." Therefore, policy will need to include a definition for "biologically incompatible." There may also need to be an additional informed consent component for donors who could have donated to their candidate, but fit into the definition of biologically incompatible and decided to enter KPD instead of doing a direct living donation.

IT Solution

n/a

Instructional Solution

Explain the practical implications of the definition of biologically incompatible - explain what pairs that term applies to and which pairs it does not.

Other Solution

Edit the agreement to participate to remove "incompatible pairs" from its description. Policy does not necessarily need to change.

Revising KPD Priority Points

Sponsoring Committee

Kidney Paired Donation

Public Comment:	2015-August
Board Date:	2015-December
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 difficultly 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. October, 2014: This project was stalled while the Work Group focused on preparing the public comment proposals for the Fall 2014 public comment cycle, but the Work Group is meeting on October 13, 2014 and will reignite the conversation surrounding revising the priority points. The goal of the October 13 discussion is for the Work Group to establish a project plan for revising the priority points, so the DOAS has a focused approach as it analyzes options and makes recommendations to the full Work Group. November 18, 2014: The KPD Work Group and reviewed potential approaches to this project in much more detail. They agreed that the DOAS will focus all of its attention on this project. The exact project plan is still not finalized. December 9, 2014: The KPD Work Group will discuss "orphan candidates" (also known as the candidates in need of a remedy for a broken KPD match) during its December 16, 2014 teleconference. As part of the phased approach to the Revising the Priority Points project, the remedy for the broken KPD match will be addressed in the first phase, and therefore tracked as part of this project form. After the December KPD Work Group call, the Design and Optimization Algorithm Subgroup (DOAS) will continue to focus on this phase of the project during its monthly calls until a remedy is developed. January 2015: DOAS is now meeting on a monthly basis (the second Monday of every month at 4pm). They agreed that orphan candidates will receive maximum priority in the revised priority points scheme. February 9, 2015: Tuomas presented his research on dynamic, future-match, failure-aware optimization. DOAS discussed developing a survey to send to KPD Work Group members for input on suggested priority points. Additionally, DOAS discussed breaking the Priority Points project into two possible phases, focusing at first on orphaned candidates, streamlining and updating

priority points schedule, basic "failure-aware" matching, and incentivizing participation. The second phase would focus on potentially expanding "failure aware" matching and incentivizing participation, in addition to adding "dynamic" matching, standardizing A2/A2B for B candidates, revisiting the donor pre-select, or awarding points for donor homozygosity and other factors. DOAS decided to push forward on a two-prong approach for the project - sending the results of the survey to Tuomas for further analysis and laying the groundwork for Phase 1. DOAS may need to request a sensitivity study to make changes to the priority points. February 2015: At the request of DOAS, UNOS staff discussed a data request with KPD Leadership. UNOS staff submitted the approved data request to HRSA. The analysis plan includes sensitivity studies using historical KPD match runs and tallying the number of negative physical crossmatches among candidates and potential matched donors currently in the system. KPD leadership would like to further discuss the survey development to ensure that it does not become burdensome. March 2015: Darren has been working on completing the data request in anticipation of the April 6th DOAS meeting. April 2015: Darren presented the results of the sensitivity study on April 6 and 15 to DOAS. Based on the results, DOAS voted to reduce 0-ABDR mismatch points from 200 to 10 (to serve as a tiebreaker), adopt a sliding scale for CPRA (range is from 0-2,000 points), remove same DSA and same region points, increase same center points from 25 to 75 points, added points for candidate and paired donor ABO, and removed antibody specificity points (-5). On April 20th, the KPD Work Group approved these recommendations for inclusion in a fall 2015 public comment cycle. May 2015: On May 11th, DOAS recommended the following changes to the priority points: assign 1,000,000 points for orphan candidates, add 75 points if the candidate and potential donor had a previous negative crossmatch, and keep prior living organ donor (150 points) and pediatric points (100 points) the same. These additional recommendations along with draft policy language changes were approved during the KPD Work Group call on May 19th. The Kidney Committee will vote on the policy for public comment on June 15th. June 2015: On June 15th, the Kidney Committee discussed the supporting data and the priority points policy changes recommended by the KPD Work Group. The Committee voted to send the policy out for public comment this August. July 2015: UNOS staff drafted and finalized the public comment document.

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.

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. September, 2014: The project is still in pilot in Region 5. To date, members who have accessed the materials have reported positive feedback. December, 2014: The Committee requested that the Pilot materials be pushed out to other Regions for further study. March, 2015: With the help of the RRB Chairs, UNOS staff has updated the slide sets to incorporate the particular regional agreements for those regions who have any in place. Additionally a presentation on the duties of an RRB Chair and an assessment for users on the materials is being developed. May, 2015: Materials have been completed. The Committee has agreed to wait until July 1st to educate all new Committee representatives who will be serving as RRB Chairs. In turn the RRB chairs will educate their RRB colleagues during the Fall 2015 Regional Meetings. Assessments on the materials will be completed immediately following the training and 30 days post training. While this project does not require formal public comment or approval, the Committee intends to update the Board on the process of implementation and the feedback received on the assessments during the December 2015 Board meeting.

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:	2016-January
Board Date:	2016-June
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. August, 2014: Potential speakers were identified based on their responses to the concept paper & forwarded invitations to present at the forum. All have since accepted & begun to collaborate on their areas of focus. The Steering Committee met via conference call to review the progress of the questionnaire results & to review and approve the final agenda for the forum. September, 2014: The Public Forum on Redesigning Liver Distribution was held in Chicago, Illinois on September 16. Approximately 197 individuals attended in person in addition to Committee Members, Steering Committee Members, SRTR, HRSA and staff. An additional 282 participated via Webinar. Presenters and participants from across the country contributed to the success of the Forum. The forum was successful in its intended purpose – to gather additional feedback, ideas and questions to help shape further policy development. The vast majority of participants agreed the OPTN should seek to ensure that candidates have timely access to liver transplantation. Opinions varied on the best metrics and methods to use in identifying and reducing geographic disparities, as well as the potential effects such efforts may have for transplant institutions in areas such as clinical practice, logistics and costs. Another theme commonly expressed was a need to optimize organ donation and utilization of available organs. The Liver and Intestinal Organ Transplantation Committee met on Sept. 17 to discuss the feedback from the forum, as well as the responses to the questionnaire distributed in June along with the concept document. The committee agreed that additional study and feedback is necessary to continue to study the issues identified. It resolved to establish four work groups, each composed partly of members of the committee and partly of additional subject matter experts, to address four key focus areas: Metrics to assess geographic disparity, Logistical/transportation considerations, Financial issues, Methods to optimize liver utilization. These work groups will develop recommendations to share with the full committee to aid in refinement of existing concepts or development of new ones. There is, at this point, no timetable for a policy proposal. It is important to note, however, that any policy proposal once developed will offer all interested parties an opportunity for additional public comment. October, 2014: The rosters for the Ad Hoc Subcommittees have been finalized, invitations circulated to potential participants and meetings have been scheduled. Meeting dates will run from November through the end of April

with the goal of each subcommittee developing recommendations to the full Committee and to the community at a public forum sometime in May 2015. December, 2014: The Ad Hoc Subcommittees began meeting, each with a review of the past decisions and analysis of the Liver Committee's previous efforts and decisions leading up to Redistricting. The Ad Hocs will continue to work to develop recommendations on their specific topics through the end of April. January, 2015: The Ad Hoc Subcommittees continue to meet via conference call and have identified several key areas for concentration of their efforts. February, 2015: The Metrics of Disparity and Optimization of Distribution Ad Hoc Subcommittee as well as the Finance Ad Hoc Subcommittee have developed formal requests for updated modeling and LSAM runs from the Scientific Registry of Transplant Recipients. The SRTR anticipates that these requests can be fufilled by mid to late May for the Committee to consider. The Committee has begun planning for the second Public Forum with a target date of late June for presentation of these updated concepts to the community. March, 2015: The Ad Hocs continue to meet via conference call to discuss and develop consensus based recommendations and suggestions for policy improvements. The initial announcement for the Forum was circulated to the community with the caveat that the date may need to be changed or cancelled dependent on the continued progress of the Ad Hocs. April-June, 2015: The Ad Hocs continue to meet via conference call to discuss and develop consensus based recommendations and suggestions for policy improvements. The Forum has been confirmed to take place on June 22nd, 2015 in Rosemont, Illinois.

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:	2016-January
Board Date:	2016-June
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. 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. August, 2014: The Committee met via conference call and began discussing the construct of a new NRB based on the 2004 model. While the policy language will be easily modified all agreed that logistics and education would be of the upmost importance. Discussion will continue at the in person meeting in September. September, 2014: The Committee met in person on 09/17/2014 in Chicago & continued the conversation on the NRB construct currently under consideration. October-November, 2014: UNOS staff began drafting a public comment document, policy proposal and updated operational guidelines in accordance with the concept embraced by the Committee and the Board. The Committee will consider these documents and vote to send them forward to public comment during their December conference call. December, 2014: The proposed public comment document, policy and operational guidelines were reviewed during the Committee's conference call. Several members expressed concern that the construct of the NRB needed more consideration before presentation to the public for comment. The Committee unanimously voted in support of withdrawing this proposal from the 2015 spring public comment cycle with the intent to redraft and circulate it for the fall 2015 cycle. February, 2015: The Committee has suggested that perhaps rather than one single national RRB perhaps they should pursue the option of incremental steps. By combining several of the current regions into "super regions" who will then have the ability to learn from one another, may better achieve the goal of increasing consistency. May, 2015: The Committee has decided to pursue the idea of "Super Regional Review Boards. They intend to discuss which regions should be grouped during their in person meeting. Minor revisions to the previously drafted proposal will be made however, the general construct will stay the same.

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.

Establish or Clarify Policy Requirements for Therapeutic Donation (originally Clarify Status of Domino Donors)

Sponsoring Committee

Living Donor

Public Comment:	2015-August
Board Date:	2015-December
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 meetings. 7/14 - Draft policy language has been developed. Planning to ask organ specific committee to review draft policy language at their fall meetings. 8/14 -Sent draft policy language to the Ops and Safety, Thoracic and Liver Committee for pre public comment feedback. Deadline for feedback is 10/31/14 10/2014 J: The issue of liver domino donors came before the MPSC this month. This project should address the membership requirements for domino donor recoveries. Does the TP need to be an approved living donor TP? The MPSC thought so and we should make that clear in the bylaws/policies. 10/14 - LDC decided to delay policy proposal one public comment cycle because the MPSC will be considered potential changing membership requirements for centers preforming domino liver donation during its December 9-11, 2014 meeting. Final proposals for public comment due 12/12/14. James Alcorn supported delaying this proposal for one public comment cycle. 1/15 - Committee had received preliminary feedback from MPSC. MPSC not concerned with domino donation occurring at non-designated living donor recovery programs. Proposal slated for August 2105 public comment. DTAC asked to comment on some comments provided by the MPSC. Committee liaison scheduled to talk with DTAC leadership. 4/2015 - During its April 2015 in person meeting the Committee supported expanding the proposal to address other categories of "therapeutic donors"

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

Changes to Transplant Program Key Personnel Procurement Requirements

Sponsoring Committee

Membership & Professional Standards

Public Comment:	2015-August
Board Date:	2015-December
Status	Evidence Gathering

Problem Statement

MPSC and JSWG discussions have prompted a number of questions about key personnel procurement requirements in the Bylaws. These questions have highlighted the following problems: Surgeons applying through the fellowship pathway who did not complete the requisite number of procurements during their fellowship, but would otherwise qualify as a program's primary transplant surgeon: The OPTN/UNOS Membership and Professional Standards Committee (MPSC) receives primary transplant surgeon applications from individuals applying through a training pathway who have completed the requisite number of procurements, but not all of the reported procurements were performed during their training period. The MPSC generally feels these individuals are qualified to serve as the program's primary transplant surgeon, but is obligated to reject these applications per the current Bylaws requirement. Primary transplant physician Bylaws that state these individuals "should" have observed three procurements: it is generally accepted that primary transplant physicians need to have some familiarity with the organ procurement process. The Bylaws support this, stating that primary transplant physicians "should" have observed three procurements, but this expectation is unenforceable as written due to inclusion of the word "should." Inconsistent key personnel procurement requirements in the Bylaws: experience with procurements involving multi-organ donors is only required of primary kidney transplant surgeons; and separately, experience in donor selection and management is only required of primary liver transplant surgeons. These surgical experiences are not exclusive to each respective organ, and it is not clear why these requirements would be specified for these isolated organs. Questionable necessity of specifying primary transplant physicians must observe multi-organ donor procurements: Bylaws pertaining to primary transplant physicians' exposure to organ procurements state that physicians should have observed three multiple organ donor procurements. The majority of deceased donors today are multi-organ donors. Looking at data from 2012-2014, 92.2 percent (23604 of 25007 total donors) of donors had more than one organ recovered. This prompted questions whether the Bylaws need to include this level of specificity, and thereby further complicating the requirements to qualify as a primary transplant physician.

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: 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 physician observation of procurements requirements among other JSWG items to be discussed is TBD. 9/22/14: Due to interconnectivity of all topics assigned to JSWG, and desire to asses all recommendations as a whole, winter/spring 2015 public comment is unlikely. MPSC will receive an update on JSWG progress at its Dec 2014 meeting. The JSWG will aim to provide all its recommendations to the MPSC in time for a final proposal to be distributed during the August 2015 public comment cycle. 12/2/14: JSWG began discussing key personnel procurement issues during its November 24th teleconference. Preliminary discussion on this topic indicated that this expectation of primary physicians should be required in the Bylaws, i.e., replace should with must. 1/27/15: After discussing preliminary feedback received from representative societies on the recommendations developed thus far, the JSWG considered its progress and the idea that it may be more beneficial to send topics out for formal consideration (public comment) as they are completed by the JSWG, instead of distributing all its recommendations at the end of the group's deliberations. The group ultimately agreed it should try this approach. The JSWG would like to have all those topics that the it has completed recommendations for as of the March 25th MPSC meeting to go out for public

comment this June. June public comment will be contingent upon (per the Rockville Document) the Joint Societies Steering Committee's endorsement of the JSWG's recommendations, and subsequent to that, the MPSC's support of the recommendations. UNOS staff is working to organize a JSSC meeting prior to the March MPSC meeting. Currently, the following topics are most likely to have complete JSWG recommendations by March: Evaluate Foreign Board Certification for Primary Surgeons and Physicians; Consider primary surgeon requirement- primary or first assistant on transplant cases; and a number of topics related to procurement requirements (requirement for primary physician observation of procurements, multi-organ procurement requirement for primary surgeons, timing of primary surgeon procurement requirement). The remaining topics will continue to be worked on by the JSWG, with aspirations for those recommendations to be distributed during the next public comment cycle. 3/9/15: JSWG has confirmed that physicians "must" have observed the procurements that are currently suggested in the Bylaws. Considering discussions about primary surgeon requirements pertaining to donor management and selection, and multi-organ donor procurements, the JSWG was also asked to consider similar language in the primary physician procurement requirements. The JSWG believed that the multi-organ procurement specificity was also unnecessary for primary physicians and could be eliminated, but that they should still be expected to observe donor selection and donor management, and that Bylaws language should remain. 3/9/15: These recommendations will be formally presented to the MPSC at its March 2015 meeting, and simultaneously distributed to the Joint Societies Steering Committee for its review and endorsement. Assuming both groups' support, draft Bylaws modified to accommodate these recommendations will be distributed for public comment during the cycle that begins August 2015. Objection to the recommendations will necessitate further discussion to reach consensus. 3/23/15: The JSWG's recommendations on this topic are included in the formal recommendations document that has been distributed to the Joint Societies Policy Steering Committee and the MPSC. This document provides the JSWG's final recommendations on all topics it has considered thus far, which entails most, but not all, of the topics assigned to this group. 3/26/15: MPSC voted in support of recommendations. 5/26/15: UNOS recently received notice that the Joint Societies Policy Steering Committee also has endorsed these recommendations. The MPSC met via teleconference on May 19, 2015, and voted on final Bylaws language incorporating these recommendations that will be proposed for public comment in August 2015. 7/2/2015: A number of topics addressing different aspects of key personnel procurement requirements will be packaged together in one proposal for the August 2015 public comment cycle- Changes to Transplant Program Key Personnel Procurement Requirements. This proposal incorporates the following topics that the JSWG discussed- Primary Transplant Surgeon Procurement Requirement Time Period, Primary Physician Observation of Procurements, Primary Transplant Surgeon Multi-Organ Procurement Requirement, Primary Transplant Surgeon Procurements Including Donor Selection and Management. This proposal has been drafted and posted for internal review. This project form, and the forms previously created for these individual topics, has been modified to reflect that all these topics are being included in one proposal. All future updates pertaining to these topics and this proposal will be provided on this form.

Possible Solutions

Policy Solution

Primary Transplant Surgeon Procurement Requirement Time Period-JSWG recommends allowing an additional two years immediately following one's fellowship to obtain the required number of procurements. If an individual still cannot meet the requirements included in the fellowship pathway, they should apply through the clinical experience pathway. Primary Physician Observation of Procurements-JSWG recommends replacing "should" with "must" thereby requiring procurement observations. Reviewing the primary physician procurement requirements in the Bylaws, the JSWG also recommends removing the multi-organ organ donor requirements for each organ and adding a requirement for primary kidney physicians that at least one observed procurement must be a living donor and one must be a deceased donor. Additionally, the requirement will be modified to state that the physician must have observed the "organ allocation and procurement processes" for these donors, as compared to observing the "evaluation, the donation process, and management of at least 3 multiple organ donors." Primary Transplant Surgeon Multi-Organ Procurement Requirement-JSWG recommends deleting multi-organ procurement requirements for primary transplant surgeons and physicians. The JSWG believes key personnel familiarity to multi-organ donors is important, but considering that multi-organ deceased donors are the norm, the JSWG concluded that multi-organ key personnel procurement requirements added an unnecessary level of detail in the Bylaws.

Primary Transplant Surgeon Procurements Including Donor Selection and Management- Upon discussing this matter, the JSWG agreed that donor management and selection requirements are not necessary to include in OPTN Bylaws, and this specific requirement should be removed from the primary liver transplant surgeon pathways. 5/26/15: The JSWG's recommendation was supported by the MPSC and the Joint Societies Policy Steering Committee. Bylaws changes to incorporate this recommendation will be distributed for public comment in August 2015.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Definition of a Transplant Hospital

Sponsoring Committee

Membership & Professional Standards

Public Comment:	2016-January
Board Date:	2016-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. Fall public comment - mixed results. Comments will be considered by MPSC on a 2/4/15 phone call. 1/20/2015 discussed with Dr. Chen & Raelene Skerda from HRSA. Will pull proposal from June Board consideration, revamp work group, and consider public comments for probable revision. Will report this status to MPSC on 2/14/15. 2/9/15: During a teleconference to review public comment feedback, the MPSC decided its proposal to define a transplant hospital needed additional work before being presented for the BOD's consideration. An MPSC working group was formed to continue working on this effort. 3/6/15 The MPSC will be updated on the efforts of the work group at its March 2015 meeting. 3/6/15 MPSC Work Group met and reconsider options for accomplishing the goals of this proposal. They considered modifying the language of the original proposal such that it would not require unique membership for each hospital under a corporate umbrella. In order to more fully inform a change of that magnitude, the work group will suggest to the MSPC that a survey of the members be conducted to gather more information about hospitals and transplant program structure. 3/26/2015 the MPSC considered the feedback from the work group and decided that a survey of the transplant hospitals should be developed with input from the TAC and Community of Practice. The next work group meeting will occur after we receive feedback from the Board on a related topic (at the June meeting). Proposal is not likely to be ready to go out for public comment again in August. 6/2/2015 The Board of directors directed the MPSC to complete the development of a revised proposal that could be circulated for public comment in the early 2016 release. 7/7/2015 MPSC work group met and discussed the framework for a revised proposal. 7/15/2015 Presented work to date to MPSC and solicited additional input. 7/31/2015 Next meeting of the MPSC work group

Possible Solutions

Policy Solution

Potential solutions for exploration: Establish bylaw language which clearly defines a transplant hospital. Options include - a transplant hospital as a single medical facility where transplants are performed; and -a transplant program as being designated for a transplant hospital - maintaining a list of requirements and requiring hospitals meet a certain minimum number of those requirements. 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 meber 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-August
Board Date:	2015-December
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. 8/25/14: JSWG is considering recommending an additional set of requirements in lieu of American board certification for practitioners to qualify as primary surgeon or primary physician. These additional requirements incorporate an expectation of continued education and demonstration of competence. 9/22/14: Due to interconnectivity of all topics assigned to JSWG, and desire to asses all recommendations as a whole, winter/spring 2015 public comment is unlikely. MPSC will receive an update on JSWG progress at its Dec 2014 meeting. The JSWG will aim to provide all its recommendations to the MPSC in time for a final proposal to be distributed during the August 2015 public comment cycle. 12/2/14: JSWG recommendations to be reported at MPSC December 2014 meeting: delete all references to "foreign equivalent" require all reported case experience to be performed at OPTN-approved transplant hospitals create additional pathway for key personnel who are not American board certified in lieu of American board certification: must meet all other key personnel requirements through clinical experience pathway provide two letters of attestation from program directors not affiliated with applying hospital obtain continuing medical education credits with self assessment comparable to what is expected for maintenance of certification by the specific American board subject to MPSC review 1/6/15: During the JSWG update at the December 2014 MPSC meeting, some members expressed concern with the recommendation that all reported experience must be performed at an OPTN hospital with respect to how this may impact small transplant programs. This feedback will be shared and discussed during the next JWSG call. 1/27/15: JSWG discussed preliminary feedback received in response to its recommendations. Ultimately, the JSWG agreed to proceed with its recommendations as is. 1/27/15: After discussing preliminary feedback received from representative societies on the recommendations developed thus far, the JSWG considered its progress and the idea that it may be more beneficial to send topics out for formal consideration (public comment) as they are completed by the JSWG, instead of distributing all its recommendations at the end of the group's deliberations. The group ultimately agreed it should try this approach. The JSWG would like to have all those topics that the it has completed recommendations for as of the March 25th MPSC meeting to go out for public comment this June. June public comment will be contingent upon (per the Rockville Document) the Joint Societies Steering Committee's endorsement of the JSWG's recommendations, and subsequent to that, the MPSC's support of the recommendations. UNOS staff is working to organize a JSSC meeting prior to the March MPSC meeting. Currently, the following topics are most likely to have complete JSWG recommendations by

March: Evaluate Foreign Board Certification for Primary Surgeons and Physicians; Consider primary surgeon requirement-primary or first assistant on transplant cases; and a number of topics related to procurement requirements (requirement for primary physician observation of procurements, multi-organ procurement requirement for primary surgeons, timing of primary surgeon procurement requirement). The remaining topics will continue to be worked on by the JSWG, with aspirations for those recommendations to be distributed during the next public comment cycle. 3/9/15: These recommendations will be formally presented to the MPSC at its March 2015 meeting, and simultaneously distributed to the Joint Societies Steering Committee for its review and endorsement. Assuming both groups' support, draft Bylaws modified to accommodate these recommendations will be distributed for public comment during the cycle that begins August 2015. Objection to the recommendations will necessitate further discussion to reach consensus. 3/24/15: The JSWG's recommendations to address the topic of "foreign board certification" and "foreign equivalent" are included in the formal recommendations document that has been distributed to the Joint Societies Policy Steering Committee and the MPSC. This document provides the JSWG's final recommendations on all topics it has considered thus far, which entails most, but not all, of the topics assigned to this group. 3/26/15: MPSC suggested that the CME with self assessment requirement should be stretched over two years, allowing a little more flexibility in meeting this requirement (e.g., 40 CMEs over two years instead of 20 CMEs over one year). The JSWG replied to the MPSC that he thought this was reasonable. The MPSC proceeded to vote in support of recommendations. 5/26/15: UNOS received notice that the Joint Societies Policy Steering Committee also has endorsed these recommendations. The MPSC met via teleconference on May 19, 2015, and voted on final Bylaws language incorporating these recommendations that will be proposed for public comment in August 2015. 7/2/2015: This proposal has been drafted and posted for internal review.

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. The JSWG recommends: delete all references to “foreign equivalent,” including those references in the case volume requirements include certification by the Royal College of Physicians and Surgeons of Canada in the list of acceptable certifications create additional, organ-specific pathways for proposed key personnel who are not American or Canadian board certified, that require the individual to: meet all other key personnel requirements included in the clinical experience pathway provide two letters of attestation from program directors not affiliated with the applying hospital obtain continuing medical education credits with self-assessment, comparable to what is expected of American board maintenance of certification for that respective field

IT Solution

n/a

Instructional Solution

n/a

Other Solution

n/a

Post-transplant performance review of multi-organ transplants

Sponsoring Committee

Membership & Professional Standards

Public Comment:	2016-January
Board Date:	2016-June
Status	Evidence Gathering

Problem Statement

Multi-organ transplants are not currently reviewed for post-transplant patient and graft survival. The PAIS/MPSC has discussed this issue recently in conjunction with discussions of programs that exist only in order to perform multi-organ transplants and are therefore, not reviewed for post-transplant outcomes. Initially, multi-organ transplants were not included in the models for post-transplant survival because the numbers were not sufficient nationally to develop a statistically significant model. The number of multi-organ transplants has increased since that time. Specifically, over the last three years, there has been an average of 460 simultaneous liver/kidney transplants per year. The committee expressed concern that a large segment of transplants was not included in the survival data used for review of programs. Some concern was expressed that multi-organ transplants may be performed to avoid that patient being included in the survival modeling.

Progress To Date

3/2014: The MPSC expressed concerns about this issue at its March 2014 meeting. A recommendation for formation of work group was made at that time and volunteers for the work group were solicited. The work group was tasked with exploring options for review of outcomes of multi-organ transplants. The MPSC also suggested there may be short term options similar to small volume program outcome reviews. 7/29/14: The Working Group had its first call to review data already compiled by the SRTR. Additional SRTR analyses were requested. The working group is exploring options for review of multi-organ transplants and requested additional information from the SRTR to help evaluate whether multi-organ transplants should be included in the existing models and if so, which organ; or whether a separate model should be used for multi-organ transplants. 11/2014: The SRTR provided data on the number of multi-organ transplants involving the liver, the numbers that would be identified if these transplants were included in existing liver model vs. separate models. The work group continues to explore the options available. The work group is exploring the option of requesting information from programs that would be identified for review for outcomes in simultaneous liver kidney transplants for the purposes of continued review of the options available for review of outcomes in these transplants. 12/2014: An update on the work group's progress was provided to the Committee. The Committee supported the work group's inclination to look at simultaneous liver kidney transplants as an example to explore the various options available for review. 3/2014: The working group reviewed additional data on SLK transplants and received an update on the activities of the Kidney Committee's SLK work group. An update of the work group's progress was provided to the MPSC. The work group recommended that a pilot be conducted using a separate model for SLK transplants and identifying programs separately for performance on SLK transplants to determine the factors that affect performance on SLK versus single organ transplants and the whether a separate review process for SLKs is needed.

Possible Solutions

Policy Solution

None

IT Solution

n/a

Instructional Solution

At the very least, there would be extensive communication through multiple media of this change (ex. policy notice, Transplant Pro, etc.). The project will be monitored as it progresses for any further instructional needs.

Other Solution

The most likely solution will be the inclusion of multi-organ transplants in an SRTR analysis of survival rates. The current bylaw regarding review of post-transplant outcomes would include review of multi-organ transplants. This solution would not require a bylaw revision.

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

Sponsoring Committee

Minority Affairs

Public Comment:	N/A
Board Date:	2015-December
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 (LKDs) 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 on hby 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. 1/17/2014: received named subcommittee members from the Living Donor Committee. 2/18/2014: Forwarded request to Ethics, Kidney, and Transplant Administrators Committee and await names of potential subcommittee members. 6/9/2014: Subcommittee convened but was unable to decide by consensus on how to define the "vulnerable population" in the context of the educational project. The committee will reconvene to review data previously reviewed by the committee with updated data provided at a later date. Research staff will also provide a formal written summary of the literature to help inform the conversations. 7/8/2014: During its in-person meeting the full MAC committee discussed the issues addressed by the subcommittee offering its thoughts on vulnerable populations and how they should be defined in the context of issues to be addressed by the committee and also, separately, in the context of the project. 9/24/2014: The Committee Leadership discussed the scope of the project during the monthly Leadership Call in September. This project is a joint workgroup comprised of the Living Donor, Ethics, Transplant Administrator and Minority Affairs Committee's. The Committee Research Liaisons are completing a literature review to be shared with the workgroup. The Committee Leadership is developing a workplan for this project at this time. The goal is to have a workplan for discussion at the October Leadership call. 01/21/2015: The Subcommittee convened via conference call to discuss data provided by Research (Risk of ESRD after LKD & specifically, Lit review of LD's representing vulnerable

populations) and discuss next steps. At the end of the call the Chair asked for 1-2 volunteers to start draft of guidance document w/ a deadline of one week from call date. The goal is to have a draft ready to present to MAC at their March in-person meeting and a final version ready to submit to Board in June. 02/04/2015: Discussed project status on the Feb. Leadership call w/ Chair and Vice Chair. To date, not volunteers from the workgroup stepped forward to draft guidance document. Per incoming Chair, requested that UNOS staff draft guidance document for leadership to review. Draft will be distributed to leadership before the next Leadership call (March 4). 02/16/2015: Draft of guidance doc sent to internal team for review. 02/18/2015: Draft reviewed by internal team; sent to workgroup for review. Workgroup conference call scheduled for today 02/20/2015: Workgroup given deadline of February 27th for revisions. Next workgroup call 03/04 03/03/2015: Took what revisions that were submitted as of Sunday, 03/01/2015 and updated draft. Circulated draft to workgroup members to review prior to call 03/04/2015 03/04/2015: Workgroup was satisfied with edits and draft and recommended that it be finalized for presentation to full MAC March 23. Internal team voiced concerns about recommendations being too general and the document not addressing the original problem or concerns identified by Committee in 2014. Research finalizing draft which will be sent to Project Lead Meelie DebRoy for review. 03/16/2015: Final draft circulated to full MAC to review prior to in-person meeting 03/23/2015: full MAC voted 12 yes to 3 no to send the final draft to June Board with little to no further edits. 04/01/2015: after discussion w/ Vice Chair and Policy Manager, it was determined to send memo out to Committees whose reps participated on workgroup for full Committee endorsement of guidance doc prior to sending to Board. Due to schedules and timeline, inadequate time to formally present document to Committees during face-to-face spring meetings. Memo drafted and sent to internal team for approval. 06/02/2015: The guidance document was presented at the BOD meeting and the BOD voted to table the document in order to develop the document further to include more evidence. The BOD agreed that this is an important document for the public, but just needs more work.

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

Public Comment:	N/A
Board Date:	N/A
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. 9/24/2014: A PAC subcommittee held it's first meeting on 8/14/2014. The Committee reviewed the scope of the project. Communications is crafting questions for a patient education document for the committee to review in the next call. PAC will do a focus question re information for a patient group during it's October in-person meeting. 9/24/2014: The joint MAC/PAC Workgroup met on 9/9/2014. The group recapped the purpose and scope of the project. The project will develop a patient-focused resource to encourage early referral for transplant, using information from the previous MAC Project, 'Educational Guidance on Patient Referral to Kidney Transplantation. The current task is to identify points to be addressed in the resource. Communications is taking the 8 questions set forth in the Guidance Document and developing plain language points to be addressed in a patient resource. PAC will vet these questions through the Committee as part of the full committee meeting on 10/20. 01/29/2015: Reviewed project with Policy and Research teams. Status: set meeting w/ Communications 02/04/2015:

Received draft of patient guide from Communications on 02/03. Forwarded to MAC Leadership for review. Regrouped w/ PAC liaison to discuss project; plan to talk in depth on how to move project forward with her on 02/06. 02/06/2015: Draft patient guide forwarded to MAC/PAC working group for comments/edits/input due by Monday Feb. 16th. 02/16/2015: Received edits from MAC/PAC members. Edits/input sent to Communications 02/19/2015: checked in w/ Communications re: status of updated draft, which was due for distribution to workgroup 02/20. *UPDATE* received updated draft from Communications, distributed to workgroup w/ final revisions due by Monday, March 2nd 03/02/2015: received revisions from MAC/PAC workgroup members, updated draft. Sent to Communications. 03/09/2015: per discussions with MAC leadership and internal team, the intention is for this project to be completed by June Board meeting. Updated anticipated BOD date 03/10/2015: VC Dr. McCauley gave update on project to POC-project to be completed by June Board meeting. Received updated draft from Communications team; sent final draft out to workgroup for review and non-substantive edits. Deadline March 16th. After which Communications team will shepherd through remaining steps, design and post to appropriate websites. This project will then be considered complete. 03/23/2015: discussed project status at in-person MAC meeting in Chicago. Encouraged to emphasize to UNOS Communications importance of keeping project moving for completion by June Board meeting. Support to have resource translated into Spanish. 03/30/2015: update from Communications: Communications finalized brochure draft and submitted to HRSA, with a request that they provide feedback by 04/03/2015. They will send to design next week. Communications recommends doing a rather limited print production, as UNOS will be encouraging transplant programs to order any quantities through our “Print-on-Demand” feature of the UNOS Store. Communications will start checking into Spanish language translation. That is a similar process but probably on a slightly later timeframe. 04/03/2015: updated internal support team of project status

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

Infectious Disease Verification Process to Enhance Patient Safety

Sponsoring Committee

Operations & Safety

Public Comment:	2016-January
Board Date:	2016-June
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 July 2014 Prep for August meeting. Gather available data on incidence. August 2014 Work group meeting held on 8/4/2014. Review of ABO current and proposed steps. Review of data. Review of critical questions in consideration of proposal development. September 2014 Work group meeting held 9/8/2014. Provided updates on relevant projects (e.g. HOPE Act). Discussed examples from OPOs and requested more information from transplant hospitals that currently conduct infectious disease verification. Will send overlay between ABO and possible infectious disease verification and ask for comments via email prior to next meeting. October 2014 Work group meeting held 10/6/2014. Continued discussion of possible infectious disease verification (IDV) requirements. Group will recommend second user verification of candidates willing to accept positive organs where screening statements are required. Group soliciting current transplant hospital practices. November 2014 Work group met on 11/14/2014 and discussed comments made on ABO proposal at OPTN/UNOS BOD meeting. Given concerns expressed over ABO and that proposal was tabled, work group will recommend that transplant hospitals and OPO develop individual protocols. December 2014 OSC leadership met and decided to postpone plans for Winter 2015 public comment pending results of revamped ABO proposal. Two safety measures should be in place pre-HOPE Act (special approved HOPE Act transplant hospital membership category and double verification of candidates willing to accept HIV positive organs through HOPE Act). January-March 2015 Public comment on ABO to be monitored. Will continue collaborative efforts with DTAC on re-executing the match when serologies change and monitoring issues related to completion of infectious disease testing. April 2015-May 2015 The work group met to discuss possible policy language choices for public comment distribution in August 2015. If the ABO proposal passes at the June 2015 BOD meeting, then language would be proposed that would add a verification of HBV, HCV, and HIV results available at the time to the pre-recovery verification (OPO) and pre-transplant verification (Transplant Hospital). An alternative to have OPOs and transplant hospitals develop organization-specific protocols in the absence of approved ABO policy changes was developed as well. The ABO proposal did pass at the June 2015 BOD meeting. This project was identified as one to possibly be put on hold.

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
This proposal may require an instructional program and will be monitored for specific needs throughout the development and implementation to determine the appropriate modality for educating members.

Other Solution
n/a

Standardize an organ coding system for tracking of organs (TransNet)

Sponsoring Committee

Operations & Safety

Public Comment:	2016-January
Board Date:	2016-June
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. October 2012: A 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 if completed, Operations and Safety will consider recommendations from the OTC on feasible system changes to implement. June 2013: 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. July-December 2013: 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. December 2013-February 2014: 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-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-July 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 three additional OPOs. Regular meeting schedule for ETT subcommittee set to meet monthly. Next meeting: August 21, 2014. August 2014 Updates given to subcommittee. Subcommittee will discuss possible policy implications and HOPE Act use at future meetings. September 2014 ETT project staff and Instructional Innovations provided training to eight OPOs at UNOS. During the two-day training, two representatives from each OPO received instruction and practiced on the beta version of TransNet-A service of the OPTN. Trainees also learned how to go back train OPO staff at home sites. Each participant passed a competency exam as well. Training for transplant hospitals is planned for October. OSC recommended that mandatory use be pursued once the system is complete. The Committee did not recommend that use be required for HOPE Act participants. October 2014 ETT project staff continued support to 8 OPOs in beta testing. Transplant hospital discovery and testing occurring. Piedmont hospital conducted the first live successful organ check in upon receipt and OR scan between organ and recipient. November and December 2014: ETT project staff are preparing for OPO voluntary nationwide roll out in March 2015. Monthly training sessions to be held at UNOS starting in March 2015. Voluntary participation requirements provided through correspondence to all OPOs. January 2015: Transplant hospital discovery, testing, and development continuing. New York and California transplant hospitals/OPOs visited by TransNet team. As of 1/28/15, 22 OPOs have signed up or expressed interest in TransNet training. Training dates are scheduled monthly at UNOS through August 2015.

Possible Solutions

Policy Solution

The OSC may propose policy mandating use following results from field testing, beta testing, and voluntary deployment.

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 requirements.

Other Solution

n/a

Limit Paper Documentation Required to be included with Organ Packaging

Sponsoring Committee

Organ Procurement Organization

Public Comment:	2015-August
Board Date:	2015-December
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

June 2013: Operations and Safety Committee received recommendation from the Ad Hoc Organ Tracking Committee. February 2014: The project was reassigned to the OPO Committee. July 2014: OPO Committee has formed a subcommittee and will begin work on this in August 2014. October 2014: OPO Committee sent a memo to the TCC and TAC and discussed the feedback. December 2014: There appears to be some real differences of opinion between the OPO community and the transplant center community so continued collaboration will be required to resolve the issues prior to August 2015 public comment. March 31, 2015 - This will be on the agenda for the in-person meeting in Chicago. June 2015 - Policy language being drafted, OPO Committee approved policy language during a conference call on June 30th.

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.

IT Solution

Again, depends on the approach determined by the committee.

Instructional Solution

n/a

Other Solution

n/a

Pancreas Underutilization (Facilitated Pancreas Allocation)

Sponsoring Committee

Pancreas

Public Comment:	2015-August
Board Date:	2015-December
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

This project has a corresponding subcommittee, entitled the Pancreas Underutilization Subcommittee. Currently, Pancreas Underutilization Subcommittee has standing, monthly calls. The Subcommittee has made numerous data requests in order to ultimately identify the reason for the increase in pancreas discards and mechanisms to cease and reverse this increase. In addition, the Subcommittee has identified areas of improvement for Policy 11.7.A Facilitated Pancreas Allocation. The areas of improvement include: Creating criteria for centers to participate in Facilitated Pancreas Allocation Creating a monitoring process for the Committee to monitor participating center's utilization of the Facilitated Pancreas Allocation, and Performing a general review and update, as needed. The Subcommittee gave a lengthy update to the full Committee at the Committee's in-person meeting on October 14, 2014. The Committee commended the work the Subcommittee has performed thus far and provided additional suggestions for areas of investigation. The Subcommittee will propose updates to Policy 11.7.A Facilitated Pancreas Allocation in a public comment proposal. The Subcommittee initially decided to release the proposed updates to Policy 11.7.A Facilitated Pancreas Allocation during the January 2016 public comment cycle. However, after further discussion, the Subcommittee thought it would be prudent to review the one-year data from the changes to the pancreas allocation system (which took effect on October 31, 2014) in conjunction with their proposed policy language changes to Policy 11.7.A Facilitated Pancreas Allocation prior to submitting the proposed policy changes to Policy 11.7.A Facilitated Pancreas Allocation for public comment. As such, the policy changes to Policy 11.7.A Facilitated Pancreas Allocation are now expected to be released for January 2016 public comment. 03/10/2015: Although one-year data from the changes to the pancreas allocation are not present; the Committee determined there was sufficient data to move forward with modifying the facilitated pancreas allocation policy. In addition, the Committee will begin work on the pancreas underutilization manuscript, but indicated this effort may require another data request. 06/03/2015: It has been determined that the Committee has adequate data and resources to produce facilitated pancreas allocation policy language by the August 2015 public comment deadlines. The full Committee will consider the Subcommittee's latest draft of this language at its June meeting. Additionally, the Pancreas Underutilization Project has been broken into two pieces. From here forward, this project sheet will reflect efforts made regarding facilitated allocation; the manuscript portion will be worked as second, separate project. 06/23/15: The full committee met and voted unanimously to approve the policy language for the August 2015 public comment period.

Possible Solutions

Policy Solution

The proposed solution requires policy changes, namely an update to the Policy 11.7.A Facilitated Pancreas Allocation.

IT Solution

The solution estimate of very small assumes that Research will provide a list of centers that are eligible once a year. The list will be loaded into a table and system will read annually to set eligibility flag. Solution also includes displaying the facilitated pancreas bypass and rollback buttons for OPOs. This would be a DR effort (less than 180) hours. If system needs to auto determine eligibility then estimate would increase to a medium because of the testing effort

Instructional Solution

This proposal may require a small instructional program and will be monitored for specific needs throughout the development and implementation to determine the appropriate modality for educating members.

Other Solution

The proposed solution was originally two-fold; it had policy and educational components. The proposed solution was to produce a document that identifies why pancreata are underutilized, and if possible, identify effective practices to rectify the underutilization. After several meetings, it became clear that the two initiatives should take place separately. The educational manuscript has become a separate project.

Pediatric Transplantation Training and Experience Considerations in the Bylaws

Sponsoring Committee

Pediatric

Public Comment:	2015-August
Board Date:	2015-December
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. On August 20, 2014, the Committee received the ASTS Task Force's recommendations. To summarize the recommendations, the ASTS felt that the OPTN had not clearly defined the problem the proposal seeks to address. They also felt that if there is a patient safety issue, then the proposed requirements are not robust enough. They mentioned that this proposal may benefit from Joint Societies Work Group (JSWG) review. Executive Committee member Peter Stock requested time to present recommendations at the full Committee meeting. On August 26, 2014, Peter Stock and ASTS Liaison Kim Gifford called into the Pediatric Committee meeting. Dr. Stock presented the ASTS Task Force's recommendations. Dr. Brewer led a discussion afterwards in which the Pediatric Committee acknowledged their shared frustration with the ASTS in not being able to secure community support for more robust training and experience requirements. However, the Pediatric Committee believes that these minimal requirements address the most egregious issue of surgeons and physicians without transplant experience serving as key personnel in predominantly pediatric transplant programs. The Committee indicated their interest in submitting this proposal for January 2015 Public Comment and committed to continuing to work with ASTS to secure their support. The Chair presented the current Bylaws proposal to the Pancreas Transplantation Committee on October 14, 2014, at their request. The Committee had not drafted pediatric Bylaws for pancreas programs. The Committee has found it difficult to propose meaningful minimal requirements for the pediatric pancreas key personnel is difficult because of the rarity of the procedure. The Pancreas Transplantation Committee Chair suggested that we draft Bylaws that explicitly state that the primary pediatric pancreas surgeon and primary pediatric pancreas physician must

meet the same requirements as the key personnel at a designated pancreas transplant program. While this may have been inferred without the added language, the inclusion of pancreas programs would make these requirements explicit. The Pediatric Transplantation Committee voted to include pancreas requirements in the pediatric Bylaws proposal (10-Support, 0-Oppose, 0-Abstentions). On September 18, 2014, UNOS staff began weekly meetings to discuss implementation of the pediatric Bylaws proposal. The Committee's October 15 and November 19 teleconferences were dedicated to discussing the implementation plan, including whether designated transplant programs without a pediatric component will be permitted to list pediatric candidates, whether an exception will be proposed for emergencies at programs without a pediatric component, and whether to include a conditional pathway for the primary pediatric physician, in addition to the primary pediatric surgeon. Initially, the Committee wished to allow any program to list pediatric candidates and provide an exception for emergencies. They also agreed to submit recommendations for conditional pathway criteria for the primary pediatric physicians (by organ) to be included in final draft language. After extensive discussion with UNOS staff regarding programming, monitoring, enforcement, and mitigation of any unintended consequences, Committee leadership decided on November 21, 2014 that programs without a pediatric component will not be permitted to list pediatric candidates, nor will the Committee propose an exception for emergencies. On December 10, 2014, the MPSC reviewed and voted to approve this proposal for public comment (24-Support, 12-Oppose, 0-Abstentions). Those opposed voiced concerns similar to those that have been raised throughout the Bylaw development process and that the Committee has systematically worked through. These concerns included the definition of a pediatric patient as less than 18 years old, access to pediatric transplantation, and quality of evidence to support either a patient safety concern or the proposed transplant caseload requirements. Those in support said that this proposal is the best progress made toward developing pediatric requirements in 20 years. The Chair encouraged the MPSC to allow this proposal to receive the benefit of broader consideration and feedback in public comment. On December 17, 2014, the Pediatric Transplantation Committee considered the feedback from the MPSC and voted to approve this proposal (12-Support, 0-Oppose, 0-Abstentions). From January 27 to March 27, 2015, the proposal was out for public comment. A majority of regions did not support the proposal, expressing concern for access to transplantation for adolescents as well as lack of evidence of a safety concern or to support the proposed requirements. Committee member outreach resulted in parents voicing their support for the proposal through individual comments on the OPTN website. Committee members have also secured the support of fellow pediatric specialists and some professional organizations, including the American Society of Pediatric Nephrology (ASPN) and the Studies in Pediatric Liver Transplantation (SPLIT) Council. The Committee will review public comment feedback during the in-person meeting on April 14 and will consider next steps. On April 14, 2015, the Committee reviewed public comment at its in-person meeting. After carefully considering and developing responses to the themes of public comment, the Committee voted to approve the proposed Bylaws without modification (16-Support, 0-Oppose, 0-Abstain). The Committee believes this proposal fulfills the long-standing need to establish pediatric requirements in the OPTN/UNOS Bylaws, while appropriately balancing the competing interests of quality of care, including patient safety, and access to transplantation for pediatric patients. On June 1, 2015, the Board failed to approve the proposal (19-Support, 16-Oppose, 0-Abstain). A majority of the Board is required to change the Bylaws, or 22 votes in support. On June 2, 2015, the President led the Board in a discussion to provide feedback and direction to the Pediatric Committee, since Board members were supportive of the need for pediatric requirements. The Board recommended that the Pediatric Committee convene a working group that includes the professional societies and work to stratify the primary pediatric surgeon caseload requirements. The Board expects the proposal to be released for public comment in August 2015 and presented to the Board again in December 2015. This recommended path forward was approved (35-Support, 2-Oppose, 0-Abstain). The Pediatric Subcommittee on Pediatric Primary Surgeon Requirements met on June 11, June 18, June 25, and July 2. The Joint ASTS-OPTN Pediatric Primary Surgeon Requirements Working Group met on June 19, June 26, and July 3.

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." Public comment t-shirt size for this project is very large

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

Proposal to Increase Committee Terms to Three Years

Sponsoring Committee

Policy Oversight

Public Comment:	2015-August
Board Date:	2015-December
Status	Evidence Gathering

Problem Statement

Currently Committee members have terms of 2 years, except for Patient Affairs, Ethics, and Transplant Administrators Committees who serve three year terms. Committee members often comment that a 2-year term is not enough time to allow follow-through on large projects that may take longer to complete. Two-year terms also often means that roughly half of the Committee needs to be educated and brought up to speed every years which is inefficient and may cause the Committee to lose important expertise or historical knowledge.

Progress To Date

2014: POC member and Kidney Vice Chair proposed the idea over dinner at the POC meeting. 12/2014: POC members asked to respond to email about this subject and while most seemed to think that there is value in an increased term to 3 years, some felt this could be achieved without mandating it but rather offering that as an option to add a year to the current 2 year terms. Many also felt that asking Chairs and Vice Chairs to serve for 6 (or 9) years is too much. Some also felt that three year terms should only be offered to the organ-specific committees. 1/15: Working on survey to send to all committees about term length to gather input to present to the POC at its March meeting. 4/2015: Initial feedback from committees indicates support for 3-year terms for committee members and 2-year terms for committee leadership.

Possible Solutions

Policy Solution

Modification to Bylaw 7.3 Terms of Standing Committee Members would be required. Currently the Bylaws mandate 2-year terms for all committees other than TCC, TAC, and Ethics, which have three year terms.

IT Solution

n/a

Instructional Solution

n/a

Other Solution

An alternative solution would be an operational change. Currently, a small minority of committee members have their terms extended. This usually occurs when the committee member is leading a key subgroup. There is hesitation to use this practice due to the requests to allow new members to participate in the committee process. Some of the above problems could be addressed by more frequently extending key committee members' terms.

Modification of the Heart Allocation System

Sponsoring Committee

Thoracic

Public Comment:	2016-January
Board Date:	2016-June
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. April 2014: Straw Man/Strategic Goal Update: The Subcommittee focused much more on waiting list mortality than on post-transplant survival in designing the straw man tiers. As such, the project form has been changed to remove "improving post-transplant survival" as a goal. This is important, because "considering developing a heart allocation score" was an initiative explicitly listed under "improving post-transplant survival" in the 2012 Strategic Plan. Once the Committee determined it was not going to pursue a HAS at this time, it also shifted towards improving waiting list mortality rates. July, 2014: Subcommittee is finalizing allocation rules so that SRTR can model the new tiers. July 24, 2014: The Heart Subcommittee submitted its first TSAM request so the SRTR can model the proposed new tiers. September 24, 2014: The Heart Subcommittee is still awaiting the results of the TSAM request. The results should be ready in time for the Subcommittee's October 24, 2014 meeting. The Subcommittee also submitted a data request regarding CPRA, which will also be ready for the October subcommittee meeting. October-November 2014: During the October and November Heart Subcommittee meetings the Subcommittee focused on identifying and prioritizing sensitized candidates. Though the data are not robust, the Subcommittee determined it should nevertheless use the data available to identify and prioritize sensitized candidates in the new heart allocation scheme. The Subcommittee is debating how those candidates should be prioritized. They have still not received the results of the TSAM. December 2014: The Heart Subcommittee is still torn regarding how to treat sensitized candidates in the new allocation scheme. They are suspending a decision until after they review the TSAM results in January 2015. January 2015: The SRTR presented the results of the TSAM to the Heart Subcommittee. The Heart Subcommittee has additional questions and will meet before their February 2015 Subcommittee meeting to address those technical questions with the SRTR. They will also begin thinking of any additional modifications they would like to see modeled, such as broader geographic sharing, so they can submit the request in February or March 2015. March 2015: The Heart Subcommittee was surveyed to see whether they all agree on the tiers as modeled. The consensus appears to be that the tiers are acceptable and should remain intact as modeled. The next focus in on geographic sharing. The Subcommittee hopes to submit a TSAM request by the end of their March 26 meeting regarding geographic sharing, but SRTR thinks it will take about 3 months to turn the request around. This would mean that the geographic sharing portion of the proposal would not be ready in time for August public comment, so the Committee will have to decide whether to release the proposal in two phases or wait until January 2016 public comment. April 2, 2015: Thoracic Committee leadership discussed the timeline for public comment. Due to the inability to get modeling results for broader geographic sharing from SRTR in time for August public comment, leadership decided the best strategy is to release the entire proposal in one piece in January 2016 to avoid confusing the community. Between now and January public comment, there will be a forum at ATC discussing the new tiers, and the Heart Subcommittee members will have other opportunities to reach out to the community regarding the tiers to build support. The public comment date on the project form is now changed to January 2016. We will keep the Board date as June 2016 for now. May 2015: The Heart Subcommittee is finalizing the allocation orders they'd like SRTR to model. The goal is to have these orders finished by the end of their May Subcommittee call. Once SRTR is working on the request, the Heart Subcommittee will continue its discussions regarding sensitized candidates, heart-lung allocation, and how to transition from status to tiers (for the BRD). June 11, 2015: The Committee finalized its TSAM request to show the impact of broader sharing. The Committee requested that SRTR model four different broader sharing sequences. While the Committee awaits the results, it will continue to refine the definitions for each of the criteria in each of the tiers, discuss potential data collection to be able to identify and prioritize sensitized candidates in the future, as well as other potential data to help create a future heart allocation score, and discuss heart-lung allocation. During its June 11 meeting, the Committee also began strategizing early out reach efforts for the Fall of 2015, including a potential consensus conference around the time of the AHA meeting.

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 proposal will require an instructional program and will be monitored for specific needs throughout the development and implementation to determine the appropriate modality for educating members.

Other Solution

n/a

Pediatric Lung Allocation Policy Review

Sponsoring Committee

Thoracic

Public Comment:	2015-August
Board Date:	2015-December
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. September 24, 2014: The Lung Subcommittee is awaiting the results of another iteration of the TSAM analysis of broader sharing of adolescent lungs. The Lung

Subcommittee believes that after reviewing the results of this TSAM, it will be able to decide whether to propose a policy for broader sharing. It has also discussed ABO incompatible lung transplants and believes it is right to go forward with a policy permitting ABOi lung transplants, modeled after the heart policy. October 31, 2014: SRTR staff informed UNOS that the TSAM will be ready for presentation during the November 20 Lung Subcommittee meeting, as long as there is SRTR staff available to do the presentation. Based on this timing, it seems impossible to have a proposal ready for January 2015 public comment. UNOS staff therefore updated the project form accordingly to schedule this proposal for August 2015 public comment. November 20, 2014: The Lung Subcommittee reviewed the results of the TSAM and debated the merits of the various sharing schemes presented. January 15, 2015: The Subcommittee has concluded that broader sharing is of benefit to pediatric candidates but is still deciding which of the broader sharing/child priority allocation sequences to propose: share both, which prioritizes 0-11 year old candidates for 0-11 year old donor lungs and prioritizes 12-17 year old candidates for 12-17 year old donor lungs, both with broader sharing; or child priority, which prioritizes 0-11 year old candidates for both 0-11 year old and 12-17 year old donor lungs, with broader sharing. The Subcommittee will reach out to the Pediatric and Ethics Committees for input before making a final recommendation to the Thoracic Committee. The Subcommittee is also discussing ABO-incompatible lung transplants, and decided to model the proposal off of the pediatric heart ABOi policy that was approved in June 2014. February 19, 2015: The Pediatric Committee reviewed the share both option and the child priority option on February 18. The Pediatric Committee supports the child priority option. The Ethics Committee is meeting in April and will discuss these options during their meeting. The Lung Subcommittee won't meet again until May, but will discuss ABOi policy over email over the next few months. April 2015: The pediatric crossover representative between the Pediatric Committee and the Thoracic Committee will present the new sharing options to the Pediatric Committee and the Ethics Committee during their in-person meetings and share feedback with the Lung Subcommittee at its May 2015 meeting. May 21, 2015: The Lung Subcommittee reviewed the draft policy language for ABO-incompatible (ABOi) lung transplantation and broader sharing of adolescent and child donor lungs. The Subcommittee confirmed the eligibility requirements for ABOi lung transplantation. These criteria, as well as the titer reporting requirements as drafted, are compatible with the ABOi heart policy approved by the Board in June 2014. The Subcommittee then discussed classification of these ABOi-eligible groups. They decided that ABOi-eligible infants would be classified as identical blood type match candidates and other eligible children would be classified as compatible blood type match candidates. The pediatric pulmonologist expressed concern that, in the drafted policy, Priority 1 infants not eligible for ABOi transplantation, but who were compatible with a donor's blood type, would appear after Priority 1, ABOi-eligible infants on the match run. While a decision was not made during the call to modify the language, the possibility of placing all infants in the same classification, regardless if they are a identical, compatible, or incompatible blood type match will be presented to the Thoracic Committee prior to its vote on June 11. While the Subcommittee discussed removing the titer limit for the older age group or allowing them to be classified with identical blood type matches, members ultimately chose to retain these more conservative criteria. The Subcommittee then reviewed both the Share Both and Child Priority drafted allocation sequences and decided to recommend Child Priority to the Thoracic Committee. The Subcommittee voted unanimously in support of the proposal. June 11, 2015: The Thoracic Committee voted to support the Lung Subcommittee's recommendations and is sending the proposal out for public comment during the Fall, 2015 public comment cycle. The only change from the Lung Subcommittee's recommendation was to call ABOi transplant "Alternative Blood Type Matching" instead of "incompatible."

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. This proposal will be monitored for specific needs throughout the development and implementation to determine the appropriate modality for educating members.

Other Solution

n/a