

**OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
June 1-2, 2015
Atlanta, GA**

**Yolanda Becker, MD, Chair
Sue Dunn, RN, BSN, MBA, Vice Chair**

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**OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, MO**

**Yolanda Becker, MD, Chair
Sue Dunn, RN, BSN, MBA, Vice Chair**

This report reflects the work of the OPTN/UNOS Policy Oversight Committee (POC) during the June 2014 – November 2014 period.

Action Items

1. Proposal to Clarify Definition of Organ Transplant and Transplant Date

Public Comment: [September 29, 2014 – December 5, 2014](#)

UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what should be reported as the transplant date, especially in regards to meeting reporting requirements in UNetSM. Members report that there is a disconnect in current definitions and actual clinical practices, and these proposed definitions will help bridge the disconnect and clarify the policy requirements.

The Committee considered and addressed public comment feedback received on its proposed language. The Committee felt that because public comment was generally supportive, no additional modifications were necessary to the language that went out in the public comment proposal, other than very minor formatting changes.

After careful review and presentation of the final language, the Committee voted in person on March 10, 2015 to recommend the new and modified definitions, as outlined in **Exhibit A**, for consideration by the Board of Directors (17 yes, 0 no, 0 abstention):

RESOLVED, that changes to Policy 1.2 (Definitions) are hereby approved, effective upon implementation and notice to members.

2. Proposal to Clarify Multi-organ Policies

Public Comment: [September 29, 2014 - December 5, 2014](#)

OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent. The organ-specific Committees are addressing multi-organ allocation issues, but the POC identified general multi-organ policies that could be clarified to support the organ-specific Committees' work, yet not interfere with the allocation issues and related language that they are addressing. Specifically, the POC proposes these changes to policy language:

- Policy 2.12.F is edited for clarity and to better explain what is required when organs are recovered. This is *not* an issue of multi-organ procurement, but organ procurement in general, so the title is changed to reflect that.
- Information in Policy 3.4.F was similar in content with Policy 3.4.C therefore these two policies were combined. With these changes, Policy 3.4.C now includes the multi-organ candidate registration requirements so that all the information is in one place.
- Policy 5.4.D says the same thing as Policy 2.12.F and so it is deleted. The first sentence in the original language is vague— "OPO's medical judgment" and not a true requirement as written and therefore justifies deletion.

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- The first sentence in Policy 5.8 is very similar to Policy 3.4.F and is not needed here.
- New section 5.8.A highlights different allocation scheme for Heart-Lung candidates and includes a cross-reference. This is not new, but it is moved out of the paragraph below for emphasis.
- New section 5.8.B clarifies multi-organ allocation and eliminates the language about paybacks that was not a true requirement and only “recommended” and is in keeping with the removal of paybacks once the new Kidney Allocation System (KAS) is implemented.
- Policy 6.4.A is better located in Policy 3.7 with the other waiting time modifications as new Policy 3.7.C. Table 6-4 is updated since most of these waiting time modifications cannot operationally be done since this is currently not programmed and there is currently no automated process to do these modifications. In addition, status to different organ types cannot transfer. For example, there is no way to equate a status 1A heart candidate’s time to an LAS score, so these sorts of waiting time modifications do not logically make sense and have never been put into practice as currently written.

The full POC met in person on March 10, 2015 to review public comment feedback on this proposal and consider the proposal. After consideration of the public comments received, the Committee voted unanimously (18 yes, 0 no, 0 abstention) to move the proposed language, as outlined in **Exhibit B**, for consideration by the Board of Directors.

RESOLVED, that changes to Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates) are hereby approved, effective September 1, 2015.

3. Policy Rewrite Parking Lot “Quick Fixes”

Public Comment: [September 29, 2014 – December 5, 2014](#)

In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and subsequently became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Policies; these issues were recorded in the rewrite “parking lot” to be addressed in the future.

This proposal identifies the “quick fixes” or easy, non-controversial changes that are currently in the parking lot and offers the corrected policy language to further clarify the OPTN Policies.

POC leadership met in person on March 10, 2015 to review public comment feedback on this proposal and consider the proposal. The public comment feedback was largely positive with one notable exception. After consideration of the public comment received, the Committee voted unanimously (18-0) to move the proposed language, without any changes to Policy 9.3.G (Candidates with Hepatocellular Carcinoma), to the Board for consideration. The lack of changes to Policy 9.3.G means that the policy will remain as is, but will be reviewed further by the Liver Committee.

In addition, after the Committee voted on the proposal in March, an OPO Committee member identified an inadvertent substantive change to Policy 16.4.A (Internal Packaging) that resulted from the Plain Language Policy Rewrite project. This unintended change added a requirement to this policy that represented a substantive change requiring that the rigid

container used in the internal packaging of organ and vessels always be sterile. This requirement was not originally in policy pre-rewrite, and in fact some OPOs will use a rigid container as the final layer and it is not required that it be sterile unless it is one layer of the required triple layer. The POC worked with OPO Committee leadership to restore the language to the pre-rewrite requirement, and the POC voted to approve this language (12 yes, 0 no, 0 abstentions) and include it in this proposal at its April 14 2015 conference call. Since this addition simply restores the policy to its original pre-rewrite requirements, the POC wanted to get this correction considered by the Board as expeditiously as possible, and thus included it as part of this proposal. All of this proposed language, as outlined in **Exhibit C**, is presented for consideration by the Board of Directors.

RESOLVED, that changes to Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.9 (Required Deceased Donor Infectious Testing), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 16.4.A (Internal Packaging), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts), are hereby approved, effective September 1, 2015.

Committee Projects

4. Proposal to Increase Committee Terms to Three Years

Public Comment: August 2015 (estimated)

Board Consideration: December 2015 (estimated)

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 year which is inefficient and may cause the Committee to lose important expertise or historical knowledge.

The Committee began the project by sending a survey to all OPTN/UNOS Committee members about term length. The POC research liaison compiled the results and presented them to the Committee during its March in-person meeting.

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The Committee reviewed the results of the survey and discussed the fact that there was surprising consensus about increasing terms to 3 years. The results included 123 responses broken down as follows:

- At large/Public- 43.0% of responses
- Regional Representative- 49.6% of responses
- Vice Chair- 2.5% of responses
- Chair- 5.0% of responses

The presentation showed the number of Committee members and the Committee represented, as well as the percentage in favor of an increase from 2 to 3 years. Approximately 85% of the responders said that they favor an increase in term length from 2 to 3 years. In addition, 91% of the responders said that they would be willing to serve a 3-year term. The research liaison also noted that 53% of the responders said that leadership terms should be different, since the overall time commitment would be longer for them.



The chair commented that it seems that people want to serve on Committees longer, but recognize that the chair and vice chair role is a huge commitment at 9-10 years total.

There is currently an informal option to renew Committee members for an additional year as an at large Committee member. Committee leadership can make this request if there is a member they feel they need to retain to complete a project or provide historical knowledge. UNOS staff have also pointed out that anyone can serve on a Committee work group, so that is another option for someone that the Committee wants to retain. In 2013 this happened 16 times, in 2014, 20 times, and in 2015, 5 times. For those Committee members who already serve three year terms (TAC, TCC, and Ethics) those Committee members feel that a 3-year term is “just right” in more than 80 percent of the cases.

The Committee determined these next steps for the project:

- Ask for each of the Committees to discuss and take a formal vote before considering the next steps for this project. The Committee Vice Chairs offered to provide the background to their Committee and ask them to take a formal vote. This will also help the Committee

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to see any variation by Committee and also register a vote and a commitment from the Committee.

- The results of the Committee votes will be presented to POC for discussion during a late spring conference call.
- The Committee will then evaluate whether this project should move forward and if so, whether the fall public comment timeline is still realistic.

Committee Projects Pending Implementation

None

Implemented Committee Projects

5. Clerical Changes

Public Comment: March 14, 2014, June 13, 2014

Board Approval: [November 13, 2014](#)

Implementation Date: February 2, 2015

Review of Public Comment Proposals

None

Other Committee Work

6. Committee Project Review

The POC continues its work in reviewing Committee projects with the aim to make recommendations to the Executive Committee about which projects the Committees should begin or continue.

The review process uses a survey for each new and ongoing project proposed by the Committees. This review process has three main goals:

1. **Ensure support of and compliance with NOTA, the Final Rule, and the Strategic Plans:** Committee projects should align with the Board-approved OPTN Strategic Plan, which sets the goals and contains many of the initiatives that drive the Committees' activities.
2. **Prioritize resources:** The OPTN, like any other organization, has finite resources and must prioritize those resources to achieve our goals. This includes:
 - Reviewing the level of work that we ask of Committee members.
 - Ensuring that there is sufficient Committee support staff available to complete the Committee projects.
 - Assessing the complexity of any projects that require programming.
3. **Ensure Collaboration between the Committees and outside organizations:** The project review process helps other Committees to become aware of and be involved in those projects that impact their constituencies. By using the POC, which contains representatives of the other Committees, this process allows each of the Committees to request early input into Committee projects. Additionally, given the broad composition of the POC, the Committee can recommend additional organizations or constituencies that the sponsoring Committee should include in the project.

Using the survey, the POC could approve, reject, and comment on a project to provide direction, or request more information.

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The Committee will provide the Executive Committee with a prioritized proposed Committee Work Plan that includes its recommended, approved projects according to each upcoming board cycle.

The POC continues to refine the Committee project review process. This year, the POC offered committees the opportunity to review new projects on an ongoing basis throughout the year during monthly conference calls. The POC reviewed all ongoing projects only once, at its spring in-person meeting.

The Committee reviewed 5 new projects since its last report in November 2014 to the Executive Committee. These three projects were reviewed at its January 8, 2015 conference call:

1. Timing Requirements for Deceased Donor Testing (DTAC)
2. Kidney Allocation System (KAS) Clarifications and Clean Up (Kidney)
3. Proposal to Increase Committee Terms to Three Years (POC)

With minimal discussion, the POC approved the Timing Requirements for Deceased Donor Testing (DTAC) and Kidney Allocation System (KAS) Clarifications and Clean Up (Kidney) projects unanimously and will recommend to the Executive Committee that these projects be approved. The Committee then discussed its proposed project to increase Committee terms to three years and approved it to move forward for further work and deliberation by the Committee. These projects will be added to the proposed Committee work plan that the POC presents to the Board at its June meeting.

POC members also reviewed a total of 48 Committee projects at its March 2015 in-person meeting: 2 new projects and 46 ongoing projects. The POC only reviewed projects that are expected to continue development beyond the June 2015 Board meeting.

At the time of this March 2015 review, the Executive Committee was working on creating the new OPTN strategic goals and communicated closely with the POC so the POC could begin considering Committee projects in light of how they align with the new proposed goals. These new goals are currently out for public comment and are priority weighted as follows:

1. Increase the number of transplants (40%)
2. Provide equity in access to transplants (30%)
3. Improve waitlisted patient, living donor, and transplant recipient outcomes (15%)
4. Promote living donor and transplant recipient safety (10%)
5. Promote the efficient management of the OPTN (5%)

While the POC did not evaluate Committee projects entirely using this proposed version of the new strategic plan, it did “tag” several projects that should be looked at more closely for either deletion or re-alignment with these new goals. The POC will consider these new strategic goals in more detail at a conference call on May 12, 2015 and work to make recommendations to the Executive Committee before the June Board meeting about how to rebalance the Committee project portfolio to better reflect the new goals and weight of each. The POC will receive information from the Committee liaisons about the projects’ alignment with the new strategic goals and the overall level of effort for the projects will also be considered to get a clear snapshot of how OPTN and Committee resources could be allocated to better support these goals.

After discussion and review led by the Committee Chair, the POC did not approve the following projects to continue:

- Timing requirements for deceased donor testing (DTAC)

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- Pancreas/Kidney/Pancreas Post Implementation Clarifications (Pancreas) Comments: Put on hold until they have time to review this and properly assess the new PAS
- Pancreas as Part of a Multi-visceral (Pancreas) Comments: Committee itself decided to put the project on hold and POC agreed.
- Pediatric to adult care transition project (Pediatric) Comments: Put on hold to reassess and come back to it if necessary.
- Develop system for review and sharing of safety events reported through multiple portals at UNOS (Ops & Safety) Comments: This is a staff-driven project and should not be a Committee project.

Some other important comments to note:

1. Recommended changing the National Liver Review Board project (Liver) goal to Increase Access to Transplant.
2. Facilitated liver placement (Liver): TCC is also discussing a lot of these same issues so the Liver Committee should seek collaboration with TCC. Also the Liver Committee should collaborate with the OPO Committee or at least have OPO representation on the appropriate Liver workgroup.
3. Definition of Transplant Hospital (MPSC): This is an important project and the POC requests that it go back out for public comment so this can get completed.
4. Other MPSC projects: The POC “tagged” the 8 other MPSC projects with the primary goal to “Promote transplant patient safety” and asked that the primary goal be re-evaluated since perhaps they could meet the “Increase Access to Transplants” goal.
5. Consider if living donor recovery hospitals should be responsible for providing care for post-operative complications (Ethics): The POC suggests renaming this project to “Consider who should be responsible for...” The POC also said the Ethics Committee needs to pay attention to what comes out of the ACOT meeting since it is likely going to discuss this issue. The following information provides summary information for all projects reviewed since last November.

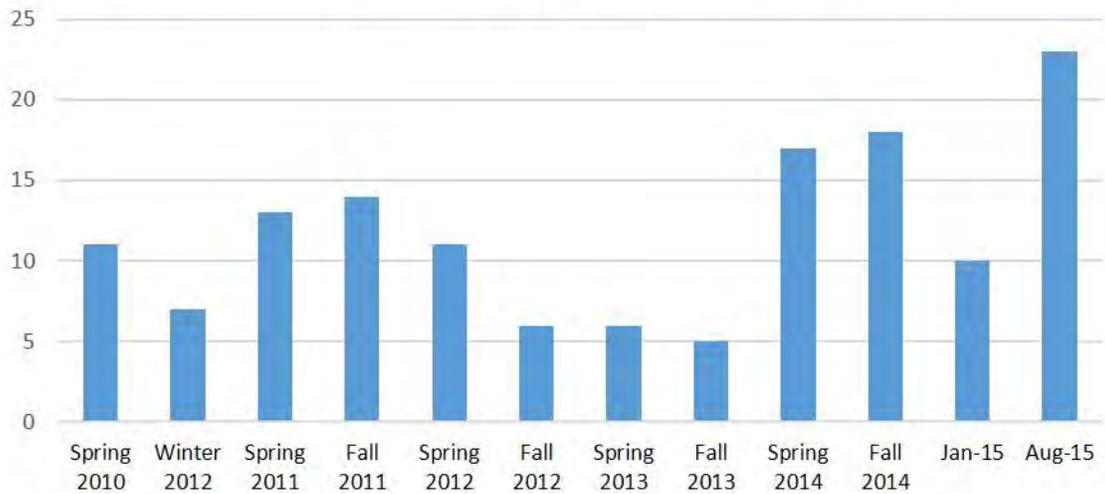
Public Comment

Projects that contain member requirements (policies, bylaws, and data collection) require public comment before they are presented to the Board. The chart below shows the number of projects that the Committees are recommending for public comment each cycle.

The trend of a large number of proposals for each public comment cycle continues for the public comment period beginning in August 2015. The graph below shows the historical volume of OPTN/UNOS public comment proposals to help put the portfolio of projects in perspective.

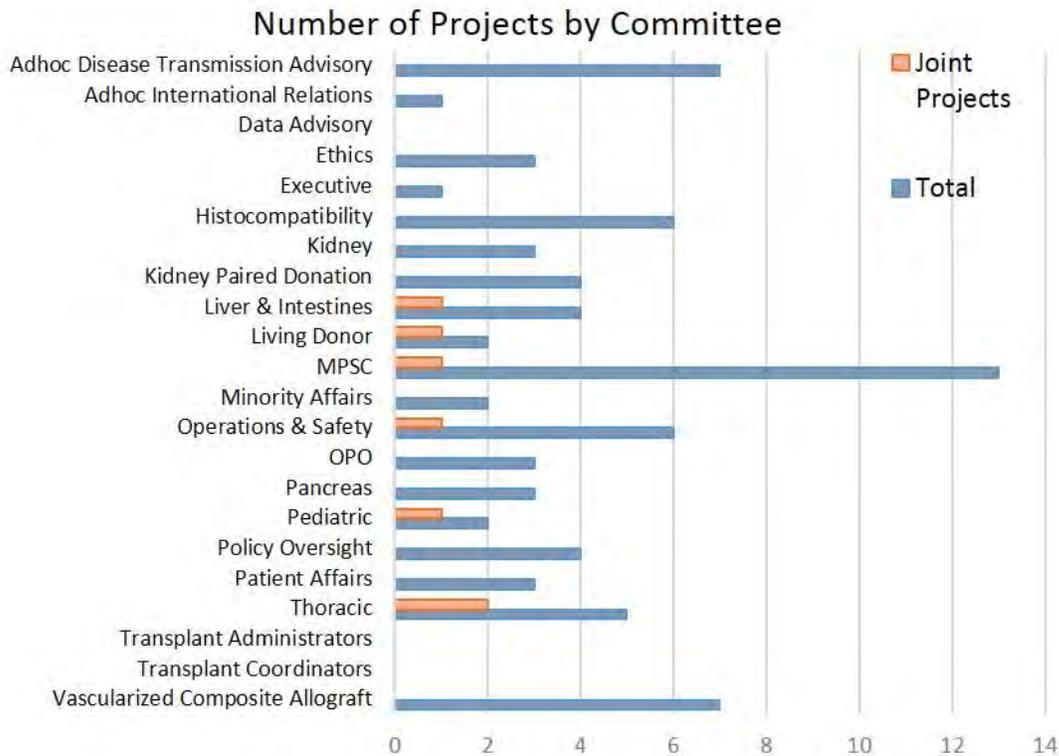
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Historical Volume OPTN Public Comment Proposals



Number of Committee Projects

All Committee projects are sponsored by at least one Committee. A project can have more than one Committee sponsor and even more collaborating Committees. To begin assessing the workload of each Committee, the following chart shows the number of projects sponsored by each Committee.



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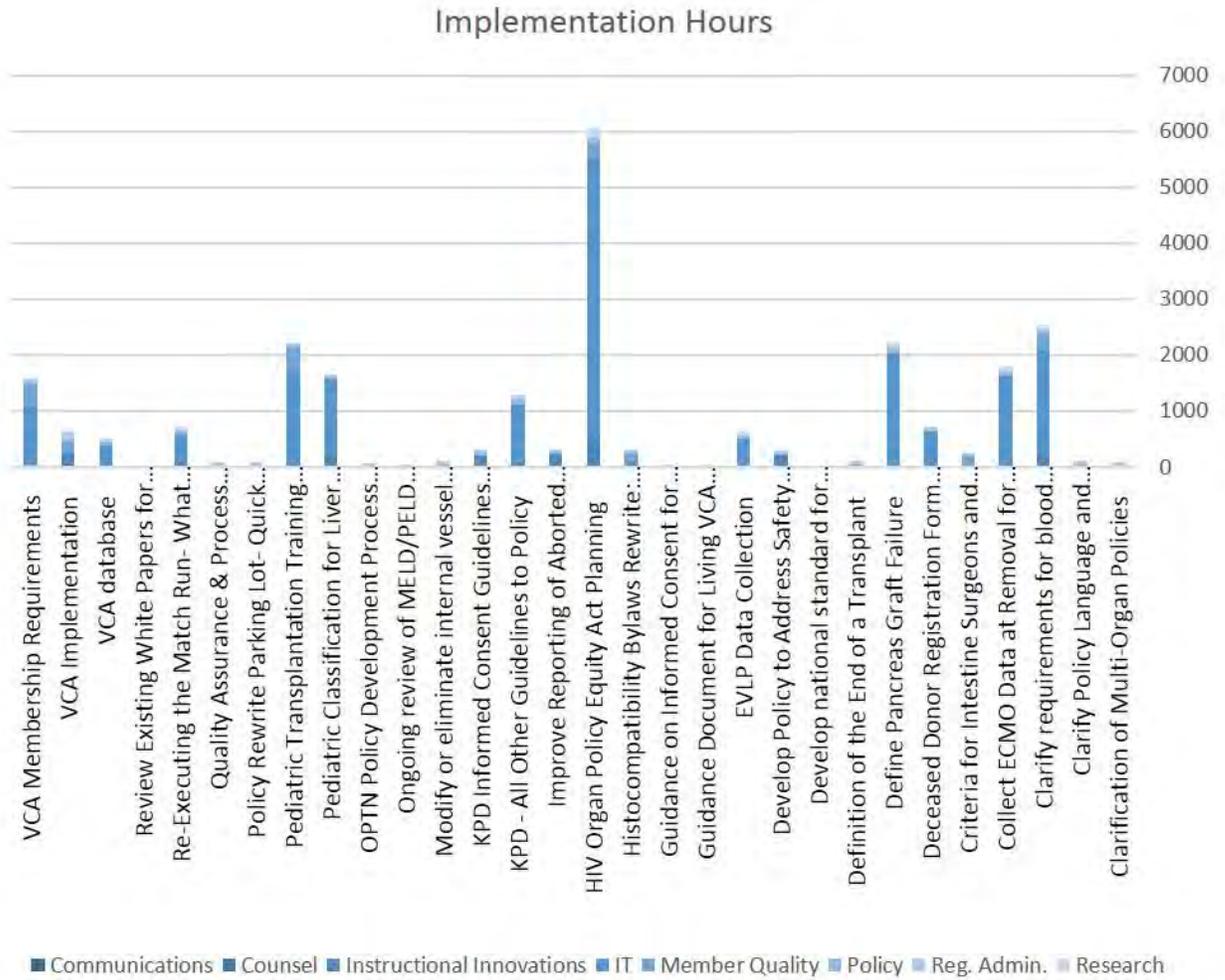
Projects per Board Meeting

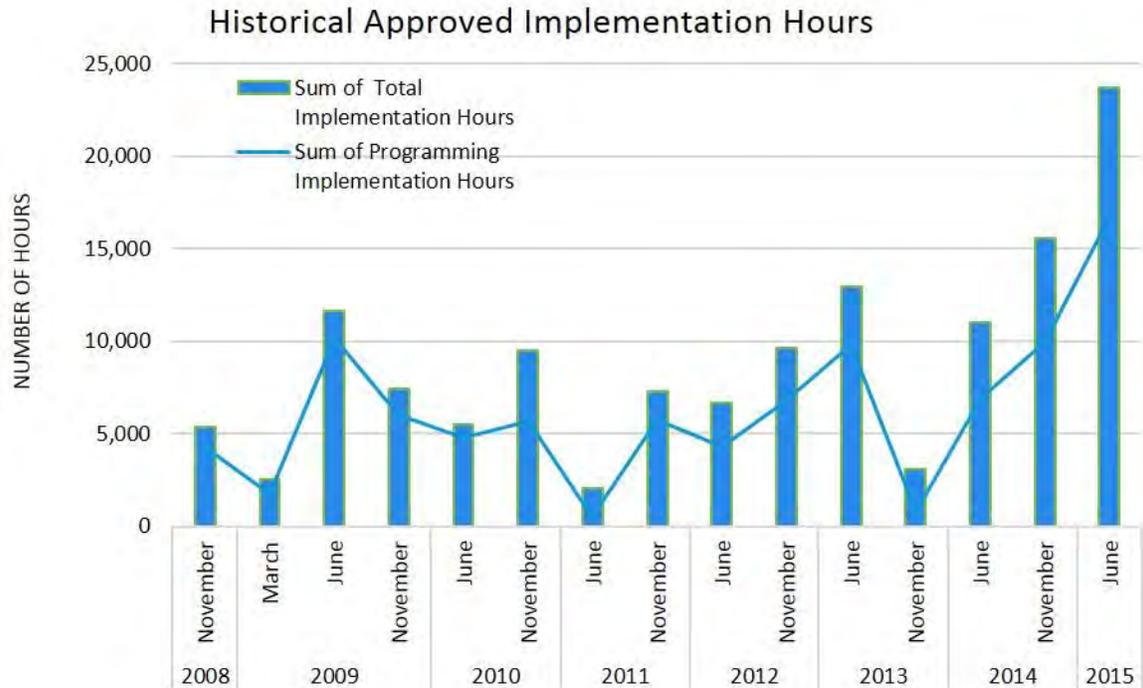
The following chart shows the volume of proposals presented to the Board for consideration at recent meetings and the projected volume for the next year. The Board schedule is largely driven by the public comment schedule; however, this is not always the case. Some proposals (ex. guidance documents) require Board approval but not public comment. Other proposals may require extensive work in between public comment and the Board meeting. The June 2015 Board meeting will be especially high because proposals from two public comment cycles (Fall 2014 and spring 2015) will be reviewed by the Board at this meeting.



Implementation Requirements for Committee Proposals

Staff provide estimates of the costs to bring the proposal to the Board and to implement the proposal. For the upcoming June 2015 Board meeting, the estimates are 23,685 hours (all implementation) and 16,680 hours (IT implementation only). If all proposals are approved at the upcoming meeting, this would be the highest level yet of total implementation hours. The June 2015 cycle is unique. It contains proposals from two public comment cycles (Fall 2014 and Spring 2015) due to OPTN planned calendar changes. The graph below illustrates the level of programming effort necessary to program all the proposals that will come before the board at this Board meeting:





7. Pre-Public Comment Proposal Reviews

The POC reviewed proposals to be distributed for public comment in January 2015 and made recommendations for the Executive Committee to consider at its January 19th conference call.

POC members completed a survey that asked questions regarding the quality of the problem statement, whether the solution addresses the problem, whether the proposal has evidence to support the problem and solution, and how well the sponsoring Committee collaborated with others. The second purpose (supporting the Final Rule and Strategic Plan), was also reviewed when the Committee proposed the project, and the public comment survey served as a check on those projects that may have evolved since they were first proposed to the POC.

The POC used the results of the survey to make a recommendation to the Executive Committee regarding which proposals should be released for public comment. The POC unanimously voted to recommend the following 10 proposals for public comment:

1. Re-Execution of the Match Run (DTAC)
2. Improve Reporting of Aborted Procedures and Non-Transplanted Organs (Living Donor)
3. Membership and Personnel Requirements for Intestine Transplant Programs (Liver)
4. Requirements Outlined in the HIV Organ Policy Equity (HOPE) Act (OPO)
5. ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Ops & Safety)
6. Modify the Sterile Internal Vessels Label (Ops & Safety)
7. Clarify Policy Language and Process for Individual Wait Time Transfer (PAC)
8. Establish Pediatric Training and Experience Requirements in the Bylaws (Pediatric)
9. Collect Ex Vivo Lung Perfusion (EVLP) Data for Transplant Recipients (Thoracic)
10. Membership Requirements for Vascularized Composite Allograft Transplant Programs (VCA)

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The POC also provided all comments about these proposals that were entered as part of the survey to the sponsoring Committee for their consideration and information.

Meeting Summaries

The Committee held meetings on the following dates:

- January 8, 2015
- January 16, 2015
- March 10, 2015
- April 14, 2015
- May 12, 2015

Meetings summaries for this Committee are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/converge/members/CommitteesDetail.asp?ID=70>.