

**OPTN/UNOS Policy Oversight Committee (POC)
Report to the Board of Directors
June 23-24, 2014
Richmond, VA**

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

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This report reflects the work of the OPTN/UNOS Policy Oversight Committee (POC) during November 2013 through May 2014.

Action Items

None

Committee Projects

1. Proposal to Allow Clerical (Non-substantive) Changes to the OPTN Bylaws and Policies

Public Comment: [March 14 – June 12, 2014](#)

Board consideration: *November 2014 (estimated)*

The current OPTN Bylaws do not mention any authority for OPTN staff to make clerical (or non-substantive) changes to policies. We currently bring policy changes to the Executive Committee in the following situations:

1. Patient safety situation requires immediate attention
2. Policy clarifications that could be interpreted as substantive changes but are in line with the committee's original intention

On occasion, clerical errors in the policies and bylaws are identified. These errors often are non-controversial issues such as obvious misspellings and mis-numbering of lists. There is nothing in the bylaws or policies that allows staff to make these non-substantive corrections. This proposal would allow staff to make non-substantive corrections to policies without requiring approval by the Executive Committee or Board of Directors. The Executive Committee would review these changes retrospectively.

While public comment is not yet complete, initial comments are supportive of the proposal. This was placed on the non-discussion agenda for the regional meetings.

2. Definition of Organ Transplant

Public Comment: *Fall 2014 (estimated)*

Board Consideration: *June 2015 (estimated)*

This proposal addresses questions that UNOS staff routinely receive 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 POC considered proposed language at its April 2014 meeting in Chicago and unanimously approved the policy language that includes definitions to be added to Policy 1.2: Definitions for the terms *organ transplant* and *transplant date*.

3. Multi-organ Allocation Policies

Public Comment: Fall 2014 (estimated)

Board Consideration: June 2015 (estimated)

The Liver, Kidney, Pancreas, and Thoracic Committees are all currently reviewing multi-organ allocation issues and policy with regard to their organ type. However, the POC is charged with updating the current policy language that deals generally with multi-organ candidates and offers. (Policy 5.8.) The POC multi-organ policy work group will focus its work on updating and clarifying the relevant current policies. POC member Dr. Mark Aeder will chair this subcommittee. The subcommittee held its first call on April 30, 2014, to begin its work.

4. Geographical Disparities in Organ Allocation

Public Comment: N/A

Board Consideration: N/A

In November 2012, the Board directed each of the “organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013.” The POC reported these measurements to the Board at its June 2013 meeting. Since that time, the Kidney Committee has continued work to refine its metric. While it is not yet certain which organ allocation system will undergo redistricting next, or when that might happen, the Kidney Committee is preparing as if kidney allocation will be the next system.

In addition to the organ specific metrics, the POC provided guidance to the Board last November on answers to the system-wide questions concerning geographical disparities and redistricting. At its in-person meeting in April, the POC received updates from the organ-specific Committees about their progress on the issue. Currently the POC is providing input to the Liver Committee on a background document to be included as part of the education and roll-out of the Liver Committee’s proposal to address geographical disparities. Other POC work on the project is on hold until the Liver Committee proposal is introduced and evaluated and the next steps for the OPTN are identified. More information about the liver redistricting project is available in the Liver Committee’s report to the Board.

5. Policy Rewrite “Parking Lot” – Quick Fixes

Public Comment: *Fall 2014 (estimated)*

Board Consideration: *June 2015 (estimated)*

The Policy Rewrite project resulted in a list of items that need substantive fixes in current policy language, but could not be addressed as part of the rewrite since the goal was to make no substantive changes during the rewrite. Some of these items are currently being incorporated into existing committee projects. This POC project will identify quick and non-controversial items from the parking lot that can be addressed in a single proposal for a first clean-up of the OPTN policies. Some of items can be categorized as follows:

- Clarifying when and why something will be reviewed by using consistent phrasing
- Converting recommended actions to requirements or moving them into guidance materials
- Standardizing timeframes
- Policy that is outdated or no longer relevant
- Policy that is inconsistent within organ groups

Those items that will take additional research or are controversial will be handled as committee projects and prioritized with other projects. Staff has begun work on this by identifying those items that can be addressed in this proposal and those items that will need further work by the relevant committees.

Implemented Committee Projects

6. OPTN Policies Plain Language Rewrite

Board Approval: *November 2013*

Implementation Date: *February 1, 2014*

The Plain Language Rewrite approved by the Board last November went into effect on February 1, 2014. Anecdotal feedback from committee members indicates that the rewrite is appreciated by the community: people can find the relevant information and understand the policies that they find.

Shortly after its release, a few editorial mistakes were identified by UNOS staff and OPTN members that resulted in corrections that were presented to the Executive Committee at its March teleconference. The Executive Committee approved the corrections, which can be seen in the resulting policy notice [here](#). The rewrite has increased the number of policy corrections made outside of the traditional policy development process, but this is not unexpected.

Other Committee Work

7. Committee Project Review

The POC reviewed new and ongoing committee projects and recommended which projects should move forward. The Committee reviewed 25 new Committee projects and 74 ongoing projects to make recommendations to the Executive Committee about whether these projects should continue.

The Committee received this summary report of Committee projects to help put their review of the projects in perspective:

Committee Projects

Spring 2014 Project Review

This report is for the Policy Oversight Committee (POC) to review along with the project forms submitted by the OPTN/UNOS Committees. It is meant to put the number, size, and type of projects in perspective as the POC makes recommendations about which projects Committees should continue to work on in the coming months.

The Process



As we have done in past years, the POC and Executive Committee will be reviewing committee project proposals prior to the June Board meeting. The purposes of the reviews are to 1) ensure that committee projects are in line with the Final Rule and support our strategic plan; 2) maximize our limited resources; and 3) coordinate collaboration between the committees.

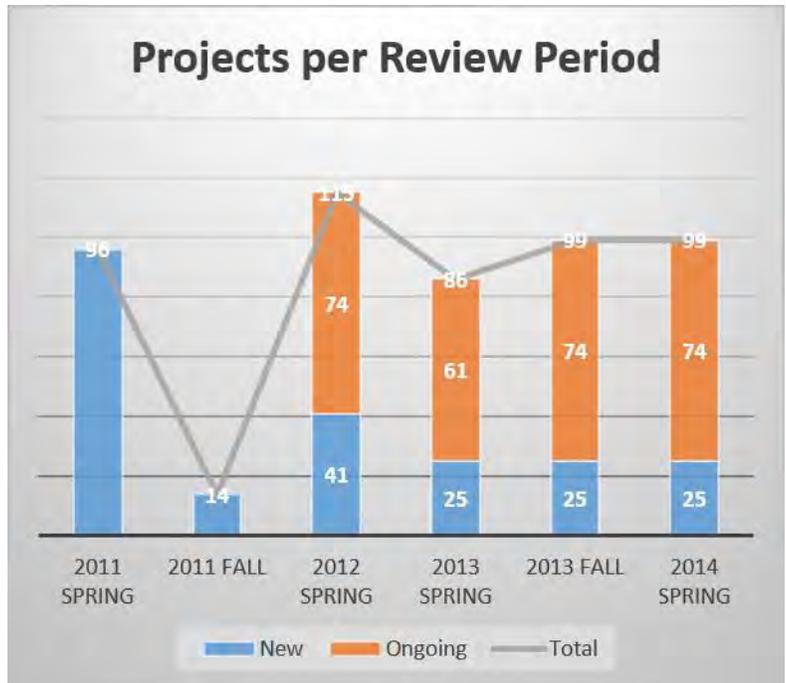
As you also know, this is not the only review that projects will receive. To put this in context, projects typically receive

reviews at the following stages:

- *Committee Projects*: New and ongoing projects are reviewed by the POC and Executive Committee prior to each Board meeting.
- *Public Comment*: Proposals for public comment are review by the POC and Executive Committee prior to submitting them for public comment.
- *Board Proposal*: Proposals for Board consideration are reviewed and voted on by the Board.
- *Implementation*: After Board approval, IT projects are ranked for implementation by the POC and Executive Committee.

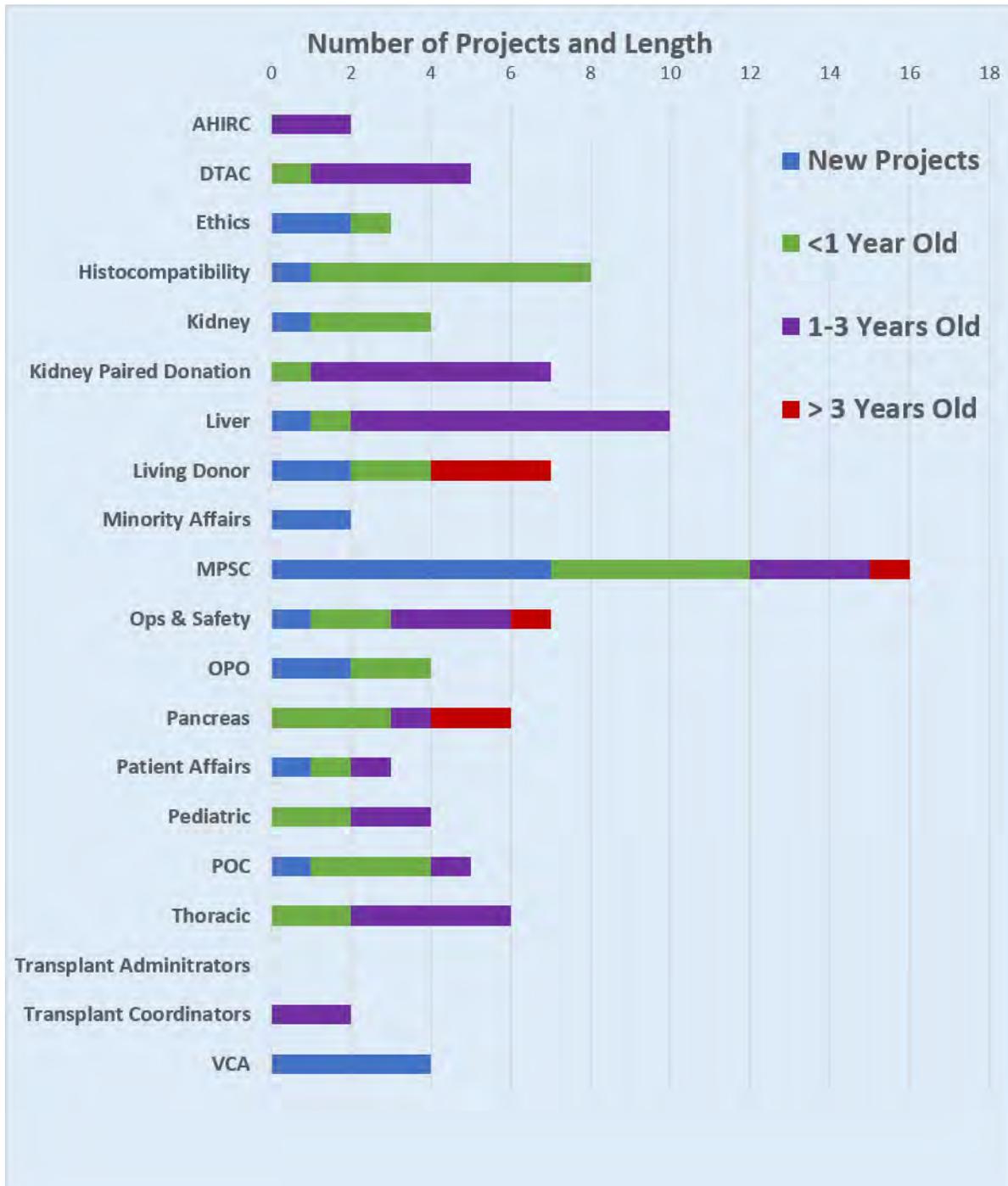
New v Ongoing

The POC started reviewing project proposals in spring 2011. The first two reviews only included new project proposals. In spring 2012, the POC began reviewing new and ongoing projects. This was originally envisioned as an annual approval process but the POC began reviewing projects twice a year in 2013.



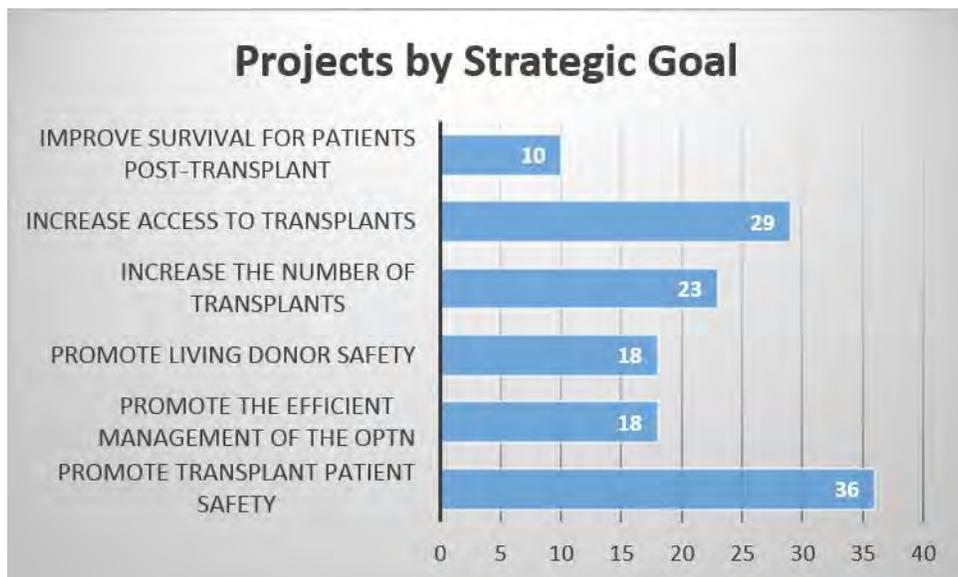
Number and Length of Committee Projects

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 and how long the Committees have been working on the projects.



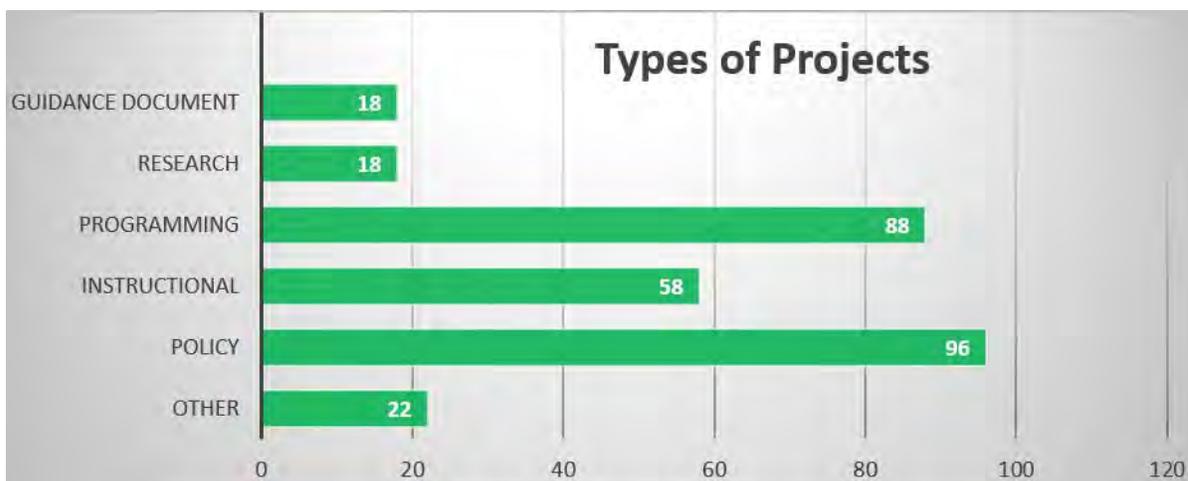
Projects by Strategic Plan

All projects must support the strategic plan. Several projects are initiatives taken directly from the strategic plan. Similar to project types below, many projects support more than one goal within the strategic plan. The following chart shows the number of projects that affect each strategic goal.



Projects by Type

Committees work on several different types of projects. Many projects will include multiple aspects. (E.g., allocation changes usually require policy, programming, and instructional aspects.) The following chart contains the number of each type of project.



Projects Requiring Programming

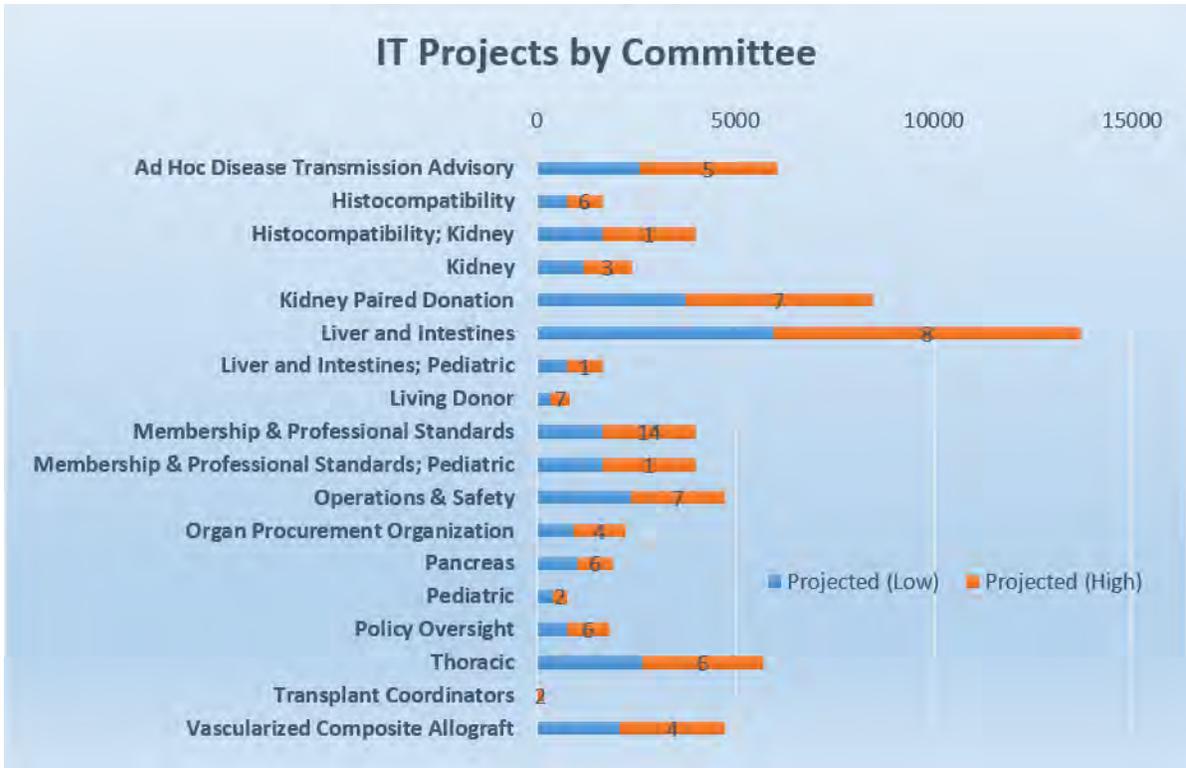
Similar to committee project reviews, IT projects will receive updated cost estimates at multiple times. In order of progression, IT projects receive the following cost estimates:

- *Committee Projects:* Prior to submitting a committee project proposal to the POC, IT projects will receive a very high level estimate for IT to implement the solution. Since these projects are in their infancy, these estimates are the first and least precise estimate.
- *Public Comment:* IT projects that require public comment will receive an estimate for IT to implement the solution. By now, the Committee has settled on a solution so the estimate is more precise. These are usually in the range of +/- 100%. These are sometimes referred to as t-shirt size estimates. These are documented in an ITSAIS.
- *Board Proposal:* Board proposals will receive an estimate to implement and maintain the solution. These costs include IT and all other UNOS departments. These are documented in a RAIS. These are the final estimates provided to the Board. These IT estimates are usually in the range of +/- 50%.
- *Implementation:* After Board approval, projects continue to receive refined estimates. These are used to schedule and allocate staff resources during the design and implementation phase. When the POC and Executive Committee meet to discuss the prioritization of IT projects, some projects will have updated cost estimates.

IT estimates are usually explained using the following gradations:

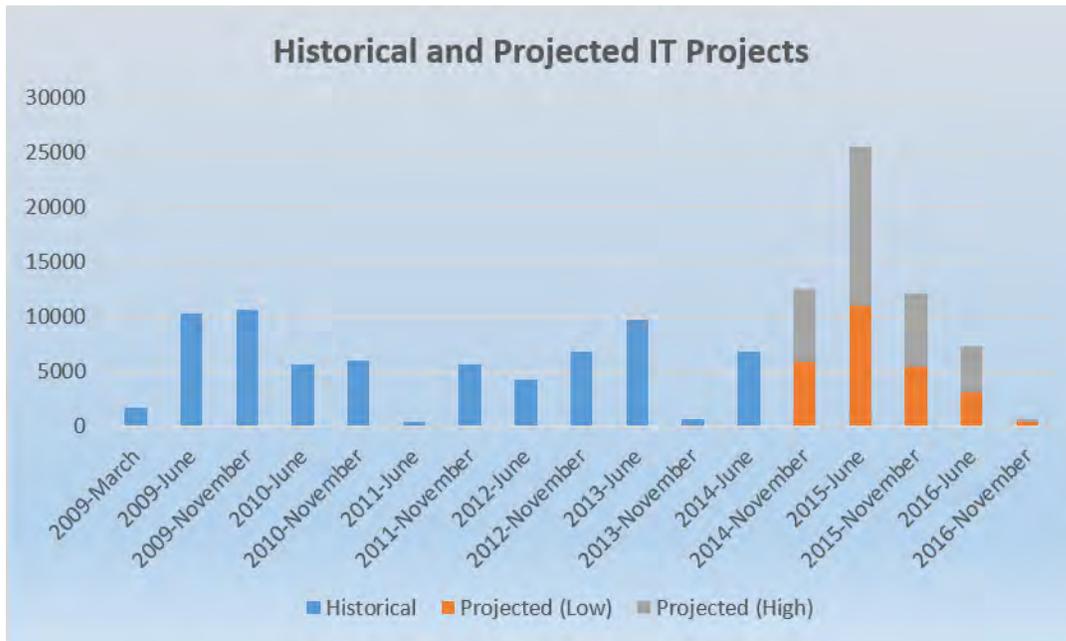
- *Demand Request (DR)t:* <180 hours to implement
- *Small:* 180-419 hours to implement
- *Medium:* 420-749 hours to implement
- *Large:* 750-1649 hours to implement
- *Very Large:* 1650-3999 hours to implement
- *Enterprise:* 4000+ hours to implement

Not all of the Committees are requesting IT projects. Because the exact number of hours cannot be predicted, IT estimates are displayed as a range (low estimate to high estimate). The chart below shows the size and number of the IT projects requested by each project sponsor.



To help put this in context, the following chart shows the size of IT projects by Board meeting. It contains the number of IT implementation hours approved at recent Board meetings and the number of IT implementation hours that the Committee plans to request at upcoming Board meetings. The total number of programming hours approved per Board meeting ranges from a low of 480 to a high of 10,120 hours. IT budgets 20-25,000 hours per

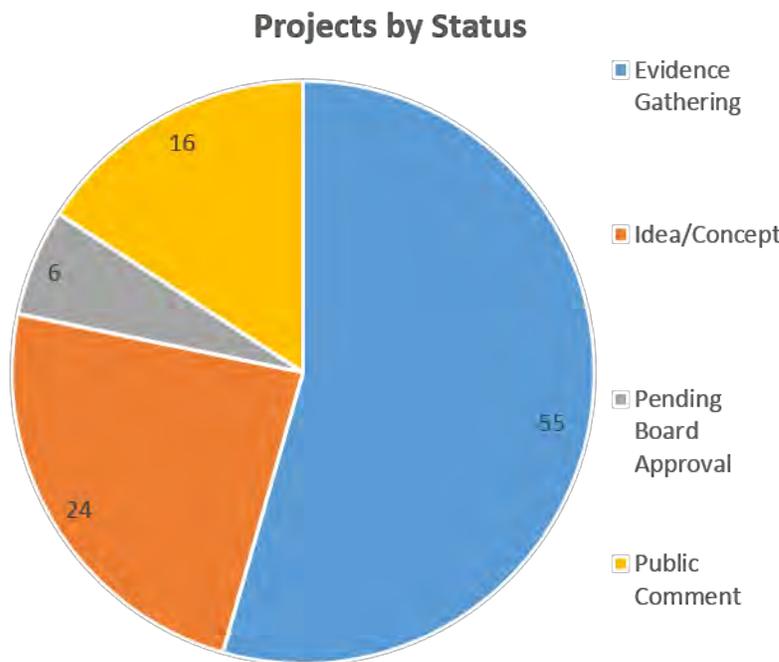
year for BOD and Committee projects. The value of 9,670 hours for June 2014 is what will be required if all the proposals brought to the Board pass.



Timelines

Status

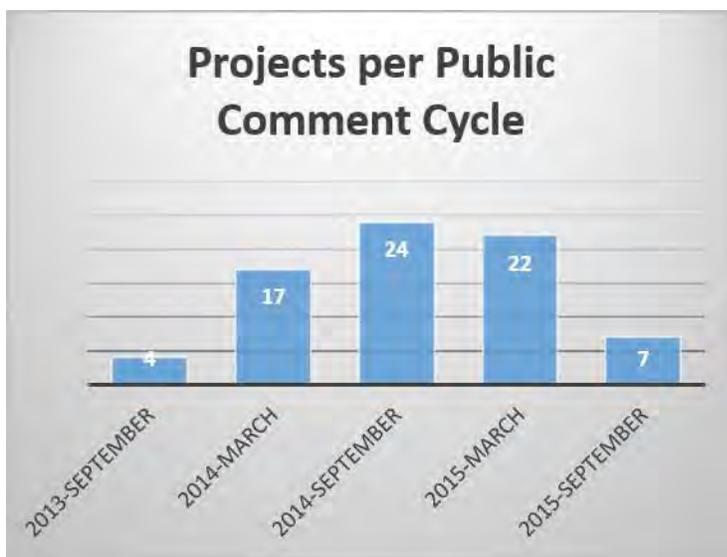
While projects are iterative and do not all follow the same timeline, they do progress through similar milestones.



- **Idea/Concept:** These are new Committee project proposals. The Committees and staff have begun work on the issue. They feel certain that there is a problem worthy of attention and have a concept of their proposed solution(s).
- **Evidence Gathering:** These are Committee projects that the Committees are actively working on, but have not yet gone to public comment or the Board. These usually make up the bulk of the project

portfolio.

- *Public Comment*: These are project proposals that require public comment (policy changes, bylaw changes, newly required data collection) and are currently out for public comment.
- *Pending Board Approval*: These are projects that are either post-public comment, are being prepared for Board approval, or some other type of final approval (e.g., an educational initiative that is nearing completion but does not require Board approval).



Public Comment

Many projects will 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. It's worth noting that the further out the projection, the less precise the estimate is. There is typically a large number of proposals that the committees are trying to prepare for the next cycle. (For example, the fall 2014 public comment cycle has a large number of proposals tentatively scheduled.) As deadlines for public

comment proposals near, several of these proposals will be pushed back one or more cycles.

Board

The following chart shows the volume of proposals headed to the Board for consideration. 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.



Updates since Last Cycle

Below provides an update of the projects to date since last cycle:

Post-Public Comment=2

Pending Board Approval = 17

BOD Approved/Pending Implementation = 5

Implemented = 2

Cancelled = 6

The Project Review Process

In April the POC reviewed 25 new and 74 ongoing Committee projects. The review process began when the Committee completed a survey for each new project and each 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, comment on a project to provide direction, or request more information. Each Committee member was asked to review approximately 6 new projects and 18 ongoing projects and rate components of the projects on a scale of 1-5. This was also an opportunity to comment on whether other Committees can contribute to the development of the project proposal.

Projects were divided into consent and discussion agenda items based on the survey results. New projects were chosen for the consent agenda based on the following criteria:

- Had an average combined score of at least 3.9
- No significant negative comments or outstanding questions
- Had a viable timeline for completing the project

Ongoing projects were chosen for the consent agenda based on the following criteria:

OPTN/UNOS Policy Oversight Committee

- Had unanimous “Yes” votes for “Should this project continue?”
- Had unanimous “Yes” votes for “Is this project making adequate progress?”
- No significant negative comments or outstanding questions

Project Review Results and Recommendations

After approving the consent agenda items, the Committee moved on to the discussion agenda. The Committee discussed each item on the discussion agenda and made the following comments that they offer as recommendations to the Executive Committee:

The POC did not support continuing the Liver Committee’s Revisiting the PELD project and the Pediatric Committee’s project “Pediatric Classification for Liver Allocation.” The POC believed the projects are duplicative, and collaboration between the two Committees needs to occur to determine the path forward and to move this project along. The POC recommends that a single jointly sponsored project replace these projects.

The Committee identified three projects that it is recommending that the Executive Committee provide more input regarding the future path and goals for these projects:

- Thoracic Committee project- Perfusion (EVLP): This project is at a crossroads, and the Executive Committee and HRSA need to explore third-party interventions and how these entities might be overseen by the OPTN.
- Joint AHIRC, IRC, and Ethics Committees project- Donor Import Policy: This project needs more input from the Executive Committee to determine how this should move forward. The POC agrees with the IRC’s plan to request further direction from the Executive Committee on this project with an examination of the specific options being proposed by the committee.
- KPD Allowing Deceased Donor Chains in the OPTN KPD Pilot Program: The POC requests feedback from the Executive Committee as well as from HRSA if this project needs to move forward. The KPD subcommittee reports that they are currently drafting a summary of the issue in order to obtain feedback from HRSA. HRSA’s feedback will help determine whether this project needs to be prioritized amongst the many other projects in the KPD Workgroup’s queue.

Other recommendations:

- MPSC-Composite Pre-Transplant Metrics: This project needs to be rewritten in a new context once KAS is fully implemented, since KAS may change the direction of this project.
- MPSC and Pediatric Committees- Pediatric Transplantation Training and Experience Considerations in the Bylaws: The MPSC and Pediatric Committees need to consult with the societies and joint societies to make sure to get their input.
- Pancreas Committee- Review Pancreas Primary Physician/Surgeon Bylaws: The POC recommended that the Committee consult with the ASTS and AST for input. (Notably, this is one of the projects the Joint Societies Steering Committee identified for review. As such, the Joint Societies Working Group will review this project and provide a recommendation to the Pancreas Committee.)

Prior to the POC review of committee project proposals, UNOS staff present the projects to the Joint Societies (ASTS, AST, and NATCO). The Joint Societies review the proposals to

“identify policies in development that have the potential to prescribe medical care.” The Societies will then have the ability to give early input on these proposals as agreed to in the 2010 Rockville agreement. This cycle, the Joint Societies selected the following projects:

- Membership & Professional Standards Committee - Approved Transplant Fellowship Training Programs
- Membership & Professional Standards Committee - Consider Primary Surgeon Qualification – primary or first assistant on transplant cases
- Membership & Professional Standards Committee - Primary Surgeon Procurement Requirement
- Membership & Professional Standards Committee - Reassess Currency Requirements for Primary Surgeons and Primary Physicians
- Pancreas Transplantation Committee - Review Pancreas Primary Physician/Surgeon Bylaws.

8. Pre-public Comment Proposal Reviews

The POC reviewed proposals to be distributed for public comment in spring 2014 and made recommendations to the Executive Committee at its March conference call. To make recommendations about the proposals, 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 Executive Committee then took these recommendations and applied a second filter: whether there were adequate resources to implement all of the proposals. The Executive Committee agreed to release all of the proposals for public comment except the Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates (Thoracic Organ Transplantation Committee). Instead, the Executive Committee asked the Thoracic Committee and staff to consider different and less costly methods to collect the ECMO data.

The POC recommended that the following proposals for public comment March 14, 2014:

1. Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation (Ad Hoc Disease Transmission Advisory Committee)
2. Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types (Histocompatibility Committee)
3. Kidney Paired Donation Histocompatibility Testing Policies (Kidney Transplantation Committee) Proposal to Cap the HCC Exception Score at 34 (Liver and Intestinal Organ Transplantation Committee)
4. Proposal to Delay HCC Exception Score Assignment (Liver and Intestinal Organ Transplantation Committee)

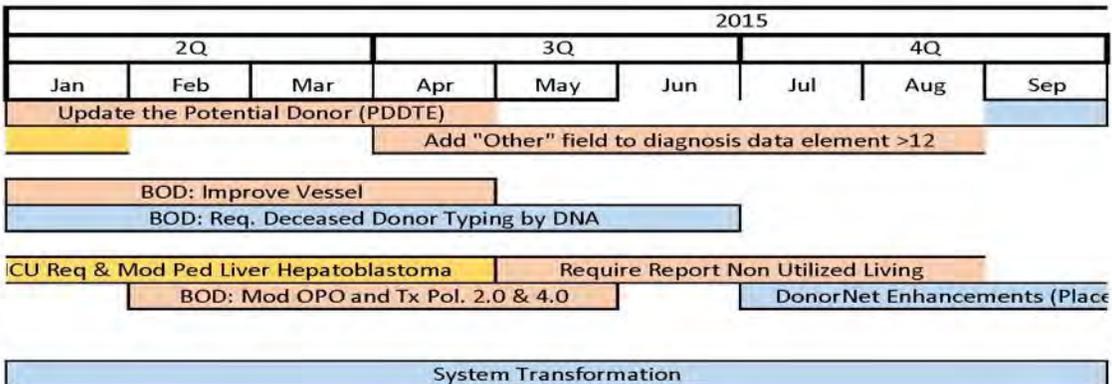
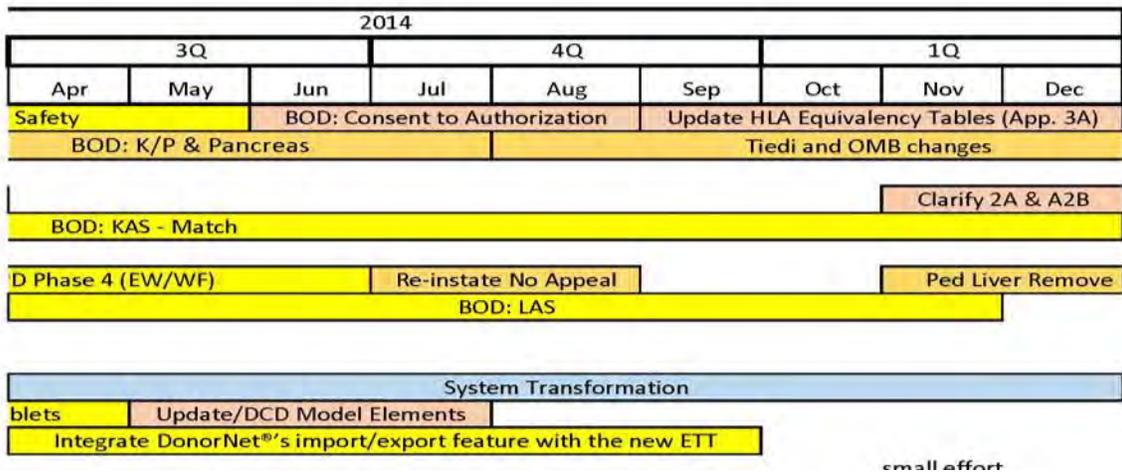
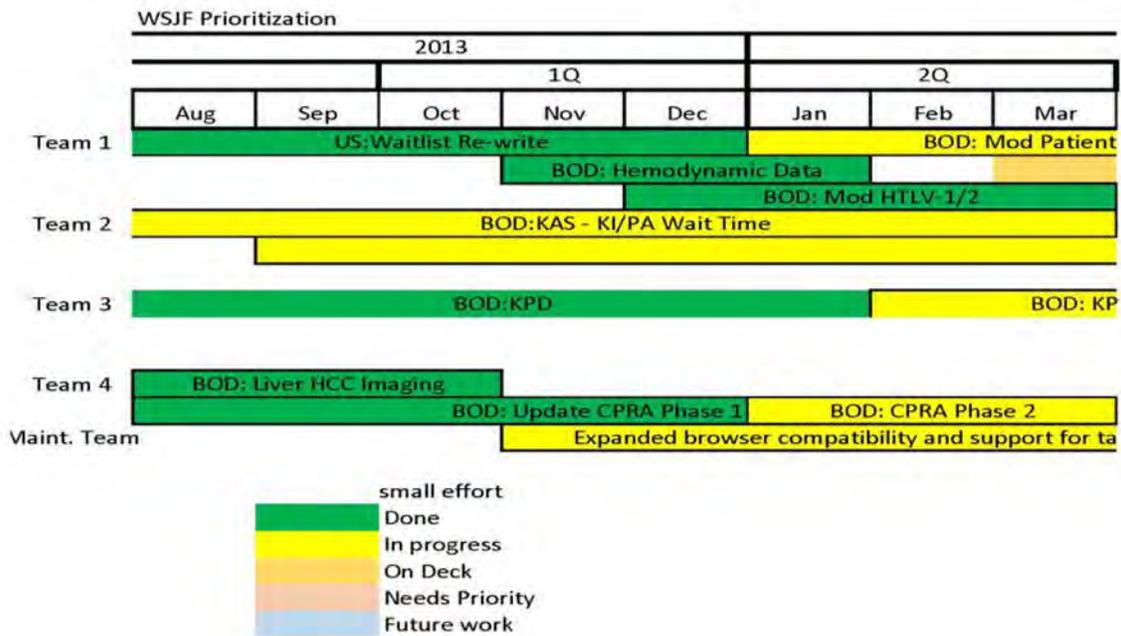
5. Proposed Membership and Personnel Requirements for Intestine Transplant Programs (Liver and Intestinal Organ Transplantation Committee)
6. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Living Donor Committee)
7. Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors (Living Donor Committee)
8. Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures (Living Donor Committee)
9. Proposal to Clarify Data Submission and Documentation Requirements (Membership and Professional Standards Committee)
10. Proposal to Allow an MPSC Recommendation to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area (Membership and Professional Standards Committee)
11. Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Operations and Safety Committee)
12. Proposed ABO Subtyping Consistency Policy Modifications (Operations and Safety Committee)
13. Proposal to Require the Collection of Serum Lipase for Pancreas Donors (Pancreas Transplantation Committee)
14. Proposal to Allow Non-substantive Changes to the OPTN Policies and Bylaws (Policy Oversight Committee)
15. Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates (Thoracic Organ Transplantation Committee)
16. Proposal to Continue the Adolescent Classification Exception for Pediatric Lung Candidates (Thoracic Organ Transplantation Committee)
17. Proposal to Notify Patients Having an Extended Inactive Status (Transplant Coordinators)

9. Prioritization of Board-Approved Projects for Implementation

After each of the last couple Board meetings, the POC has made recommendations to the Executive Committee regarding the order in which Board-approved projects should be programmed into UNetsm. All of the projects will be implemented, but resource constraints mean that they cannot all be implemented at the same time. Therefore, the POC and Executive Committee have collaborated to prioritize the schedule.

In March, the Committee completed a review of 9 board-approved projects awaiting programming and made prioritization recommendations based on this review to the Executive Committee at its call on April 9, 2014. IT staff provided an overview of its current project schedule as shown on the next page:

OPTN/UNOS Policy Oversight Committee



OPTN/UNOS Policy Oversight Committee

The POC has used different methods to prioritize these projects. This cycle, the POC used a Weighted Shorted Job First (WSJF) methodology. In reviewing the final prioritization ranking that resulted, the POC had concerns that too much value was perhaps being placed on the size of the project rather than the business (or clinical) value to the transplant community. Rather than provide the Executive Committee with that prioritization, the Committee voted to provide the prioritization of the projects based solely on the POC's perception of business value. This prioritization is shown below:

Board Approved Project	Business (Clinical) Value as assessed by POC
1. Modify OPO and TX Center Requirements for Screening, Communicating, and Reporting all Potential or Confirmed Donor-Related Disease & Malignancy Transmission Events (DTAC)	9.5
2. Update HLA Equivalency Tables (Appendix 3A) (Histocompatibility)	9.1
3. Update the Potential Donor-Derived Transmission Reporting in the Improving Patient Safety Portal (DTAC)	7.9
4. Improvements to Vessel Disposition Reporting (Ops and Safety)	6.8
5. Update and Clarify Language in the DCD Model Elements (OPO)	5.5
6. Clarify Data Entry Screens for A2 and A2B in Unet (Ops and Safety)	5.0
7. Require the Reporting of Non-utilized Living Donor Organs & the Redirection of LD Organs (Living Donor)	4.8
8. Add "Other" field to Lung Diagnosis Data Elements for Candidates less than 12 Years of Age (Thoracic)	3.3
9. Terms "Consent" changed to "Authorization" in Policy (OPO)	3.3

While the POC believed that the WSJF framework is a useful tool, the POC also felt that more discussion into how the job size and cost should be weighed when prioritizing projects was necessary, and explored the issue more at its Committee meeting in April. The discussion included the following points:

- The POC discussed the difference of rankings based on the POC's perceived business value versus the consideration of the POC's business value as well as the size of the job and time criticality. POC questions who is best able to consider each component of the WSJF methodology. *The POC recommends that if the POC continues to use the WSJF methodology, that the POC determine the business/clinical value, and staff determine the other components of the WSJF (job size, time value, and risk reduction).*
- The POC, with guidance from the Executive Committee, needs to be clear about how to prioritize projects. The POC also discussed whether we need to continue to do this based on the projection that the backlog will be completed in the next 18 months. *The POC agreed that there will always be some sort of backlog, so we will need a clear and consistent methodology for the POC and Executive Committee to prioritize the implementation of projects.*
- The length of time from Board approval to implementation is not something that has always been considered in prioritizing projects for implementation. However, the POC agreed that building in time from approval is important and should be considered as part

of risk reduction. If something is still not programmed at 18 months from Board approval, we should make that a priority. *The POC recommends that we build in an expectation that projects will be initiated within a year, and those projects that are not will be escalated in terms of risk reduction.*

- The POC discussed when is the appropriate time to filter and schedule projects for implementation (initial project reviews, public comment, at the Board meeting, after Board consideration, etc.). The POC discussed setting expectations for when projects will be implemented. It may be that we don't say "no" to projects, but say we won't be able to get to something, so slow the process down. Addressing geographical disparities is a good example: it's not going to get done until KAS is done, and kidney geography won't get done until liver geography gets done. *The POC recommends that there be a multi-year plan for large committee projects, when they are scheduled for Board consideration, and when they will be implemented.*
- The POC discussed IT's plan to clear the backlog in the next 18 months and requested that IT staff provide regular updates about its progress in clearing the backlog relative to their projected timeline.

Meeting Summaries

The Committee held meetings on the following dates:

- February 7, 2014
- March 19, 2014
- April 16, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=70>.