

**INTERIM REPORT of the
OPTN/UNOS POLICY OVERSIGHT COMMITTEE**
Conference Calls on July 19th and August 9th, 2011

1. **POC Orientation.** An orientation was held by conference call on July 19th, 2011. Highlights of the orientation included:
- OPTN Regulatory Framework
 - OPTN Key Goals
 - OPTN Tasks
 - Committee Goals and Priorities for 2011/2012
 - SRTR
 - UNOS Research Department

Committee members were given an overview of the policy proposal review process. The POC will have a more active role in the policy development process and provide early feedback on public comment proposals prior to Executive Committee review and prior to distribution for public comment. This new process includes a revised scorecard (*Exhibit A*) which was initially used to review and prioritize committee projects in the spring of 2011.

2. **Review of Public Comment Proposals.** During its August 9, 2011 conference call, the POC reviewed the policy proposals distributed for public comment in January and March of 2011.

It was noted that this proposal was separated into two proposals following distribution to the POC. The concepts remained the same with the main change being the creation of a new Status 1 category instead of the tiered regional share for MELD/PELD scores of 35 or higher proposed in the original document.

- Proposal to Extend the “Share 15” Regional Distribution Policy (*Liver and Intestinal Organ Transplantation Committee*)
The POC supported this proposal moving forward to public comment. POC vote: 11 in favor, 0 opposed, 1 abstention.
- Proposal For a New Category of Status 1 Liver Candidates (*Liver and Intestinal Organ Transplantation Committee*)
The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

(Scores based on original proposal review)

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	1.5
Target Population Impact	1.5
Project Plan/Collaboration	1.8
Cost/Benefit	1.7

Weight: 1.8 (15.3 total score)

- Proposal to Clarify Requirements for Waiting Time Modification Requests (*Kidney Transplantation Committee*)

There was a question raised about how this is different from the rewrite process. It was noted that the Kidney Committee gets approximately 25 requests a year and a lot of them are submitted with incomplete information. The intent of clarifying the policy is to improve the process for reviewing the requests and allow for better member compliance with the requirements. The POC recommends that the Kidney Committee make it clear in the proposal that this is part of the overall strategy of clarifying the policies and that moving this forward now will be beneficial to improving the process.

The POC supported this proposal moving forward to public comment. POC vote: 10 in favor, 1 opposed, 1 abstention.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.3
Proposed Solution	1.6
Target Population Impact	0.8
Project Plan/Collaboration	1.3
Cost/Benefit	1.8

Weight: 1.5 (10.5 total score)

- Proposed Revisions to and Reorganization of Policy 6.0 (*Ad Hoc International Relations Committee*)

The POC *did not* support this proposal moving forward to public comment. The POC agreed there needed to be a more focused problem statement and solution statement. There was a suggestion made that this issue could be approached in two phases. First gain consensus about what needs to be changed in the policy and then implement those changes. It might also be necessary to separate the issues that are not debatable from those that might be controversial.

The POC *did not* support this proposal moving forward to public comment. POC vote: 0 in favor, 12 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.3
Proposed Solution	1.3
Target Population Impact	1.0
Project Plan/Collaboration	1.3
Cost/Benefit	1.5

Weight: 1.2 (7.68 total score)

- Modify Policy 3.7.3 and 3.7.4 to include 24-hour downgrade period (*Thoracic Committee*)

The POC supported this proposal but suggested a minor modification to the policy language. The section of policy regarding status changes is clear but might be improved if placed earlier in Policy 3.7.3. Suggested language was “these statuses are valid for 14 days or until the candidate continually meets the requirements to be status 1A or 1B.”

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.8
Proposed Solution	1.8
Target Population Impact	1.4
Project Plan/Collaboration	1.8
Cost/Benefit	2.0

Weight: 1.6 (14.08 total score)

- Update CPRA (*Histocompatibility Committee*)

The POC supported this proposal but suggested that the following information about the number of affected candidates be included in the proposal:

“The update of the cPRA will make allocation more equitable for many patients who are disadvantaged by limitations in the current system. These include 500 patients that will receive 4 points in the allocation system for exceeding 80% cPRA when the frequency tables are updated to better reflect current typing and HLA frequencies. This proposal would also affect at least 11% of candidates who have HLA-C unacceptable antigens; because these patients do not receive the allocation benefits provided to patients with HLA-A, -B, DR, or DQ unacceptable antigens. This is a minimum estimate because some centers do not enter HLA-C unacceptable antigens because it does not affect the cPRA. In the current system, 0% cPRA can be assigned to patients who have HLA antibodies including some with high levels of HLA antibodies. This can be misleading and can have consequences for UNOS data analysis as well as misunderstandings at transplant centers. Addition of a single data entry box will remedy this problem.”

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.6
Proposed Solution	2.0
Target Population Impact	1.8
Project Plan/Collaboration	1.8
Cost/Benefit	1.8

Weight: 1.8 (16.2 total score)

- Correct Bylaws and Policies Related to HLA Labs (*Histocompatibility Committee*)

The POC supported this proposal but did have concerns about not addressing all the issues with the bylaws and policies at one time. Following a brief discussion, the POC agreed with the Histocompatibility Committee’s strategy to fix some of the major issues with the policies and bylaws before the rewrite project versions are released for public comment. It was also noted that certain policy sections can be removed from the rewrite project if additional work needs to be done to correct major flaws or outdated language.

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.6
Proposed Solution	1.8
Target Population Impact	1.8
Project Plan/Collaboration	1.6
Cost/Benefit	1.2

Weight: 1.8 (14.4 total score)

- Alternate Label for Perfusion Machines (*OPO Committee*)

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	2.0
Target Population Impact	1.8
Project Plan/Collaboration	2.0
Cost/Benefit	2.0

Weight: 1.8 (17.64 total score)

- Proposal to Change the term “Consent” to “Authorization” throughout policy when used in reference to organ donation. (*OPO Committee*)

The POC supported this proposal and noted that this change is important because of the issue of living donor informed consent and the need to clearly differentiate between informed consent and the authorization of individuals to donate organs.

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	2.0
Target Population Impact	1.8
Project Plan/Collaboration	1.8
Cost/Benefit	1.6

Weight: 1.4 (12.88 total score)

- Imminent & Eligible Death Data Collection (*OPO Committee*)

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.8
Proposed Solution	1.8
Target Population Impact	2.0
Project Plan/Collaboration	1.8
Cost/Benefit	1.8

Weight: 1.5 (13.8 total score)

- Proposal To Establish Requirements for the Medical Evaluation of Living Kidney Donors (*Living Donor Committee*)

There was some concern about the requirement to perform all tests on every potential donor. There are many occasions where donors are ruled out after only one or two tests or following psychosocial screening. Does this requirement only apply to those who go on to donate? As written, the proposed policy is not clear about whether auditors will look at charts of donors that do not go on to donate an organ, although it was noted that CMS (Centers for Medicare and Medicaid Services) will occasionally request to look at those charts as well. It was noted that CMS reviews policies from a different perspective so it would be beneficial to make the policies as clear as possible.

The POC supported this proposal moving forward to public comment. POC vote: 11 in favor, 1 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	1.8
Target Population Impact	1.4
Project Plan/Collaboration	1.6
Cost/Benefit	1.6

Weight: 2.0 (16.8 total score)

- Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors (*Living Donor Committee*)

The POC supported this proposal but did have concerns about the duplication of efforts between the OPTN and CMS. It was noted that the OPTN is the entity that should be establishing the standard of practice within the system to protect living donors. CMS has their minimum standards for reimbursement but they rely on the OPTN to evaluate things in a comprehensive manner and to look at all aspects of living donor protection. It was noted that there is recognition by the organizations involved that there is a certain level of overlap between CMS and the OPTN. There is currently no OPTN policy for the informed consent of living donors and that is something the OPTN has been developing.

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.8
Proposed Solution	1.6
Target Population Impact	1.6
Project Plan/Collaboration	1.8
Cost/Benefit	1.8

Weight: 1.6 (13.76 total score)

- Proposal To Establish Minimum Requirements for Living Kidney Donor Follow-Up (*Living Donor Committee*)

The POC supported this proposal and understands the importance of this issue. This proposal reinforces the need to develop a contract with living donors with the expectation going forward. The timeline for implementation gives centers who are continuing to do living donor transplants sufficient time to change the culture and develop relationships with living donors to help meet these expectations.

The POC supported this proposal moving forward to public comment. POC vote: 12 in favor, 0 opposed, 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	1.5
Target Population Impact	1.5
Project Plan/Collaboration	1.5
Cost/Benefit	1.8

Weight: 1.8 (14.94 total score)

Stuart C. Sweet, MD, PhD, Committee Chair
St. Louis Children's Hospital

Robert A. Hunter, MPA
UNOS Staff, Policy Analyst

Attendance

Name	Position	July 19	August 9
Stuart C. Sweet, MD, PhD	Committee Chairman	X	X
Carl L. Berg, MD	Committee Vice-Chairman	X	X
Jonathon A. Fridell, MD	At Large	X	X
Kristie A. Lemmon, MBA	At Large	X	X
Richard N. Formica, MD	At Large	X	
Tim Shain	At Large	X	X
Hueng Bae Kim, MD	At Large	X	
Meelie A. DebRoy, MD	At Large	X	X
David Mulligan, MD	At Large	X	
Richard E. Pietroski, MS, CPTC	At Large	X	X
Amy Waterman, PhD	At Large	X	X
Steven Webber, MBChB	At Large	X	
Nancy Metzler	At Large		X
Lee Ann Baxter-Lowe, PhD, ABHI	At Large	X	X
Jean A. Davis	At Large	X	X
Laurie Williams, RN, BSN, CPTC	At Large	X	X
Peter Reese, MD	At Large		X
Michael D. Green, MD, MPH	At Large	X	
Charles Mowll	At Large	X	
Christopher McLaughlin	HRSA		X
Robert Walsh	HRSA		X
Monica Lin	HRSA		X
Ba Lin	HRSA		X
Bertram L. Kasiske, MD, FACP	SRTR	X	X
Jon Snyder, PhD, MS	SRTR	X	
Tabitha Leighton	SRTR	X	X
Robert Hunter	UNOS, Committee Liaison	X	X
Brian Shepard	UNOS, Director of Policy		X
Erick Edwards, PhD	UNOS, Assistant Director of Research	X	X
Ciara Samana	UNOS, Assistant Director of Policy		X
Lori Gore	UNOS, Histocompatibility Committee Liaison		X
Vipra Ghimire	UNOS, Thoracic Committee, AHIR Committee Liaison		X
Ann Harper	UNOS, Liver-Intestine Committee Liaison		X
Lee Bolton	UNOS, Living Donor Committee Liaison		X

Committee Project /Policy Proposal Scorecard

OPTN Key Goals

Promote Transplant Patient Safety
 Promote Living Donor Safety
 Improve Post-Transplant Survival
 Increase Number of transplants
 Increase Access to Transplants

Score one of the following three questions

- Does the proposal align with one or more OPTN Strategic Goals and should proceed to public comment? If yes and has potential for significant impact score a 2, if potential impact unclear score a 1.
- Does the proposal align with one or more OPTN Strategic Goals but needs further assessment? If potential for significant impact score a 2, if potential impact unclear score a 1.
- No clear alignment to an OPTN goal, has a low cost/benefit, score a 0.

Significance of the problem /Quality of supporting data (PC proposals):

- **0** - Problem unclear and / or supporting information / data not adequate
- **1** - Problem somewhat vague and / or supporting information / data incomplete.
- **2** - Problem clearly stated, solid background / supporting data

Proposed Solution:

- **0** - Proposed solution unlikely to be attained and / or will not clearly address identified problem
- **1** - Proposed solution difficult to attain and / or will only partially address identified problem
- **2** - Proposed solution is achievable, will effectively address identified problem

Target Population Impact (i.e. candidates, recipients, transplant programs, OPOs):

- **0** - Project affects a small percentage of targeted population or special needs population (peds, minorities) and / or is likely to provide minimal improvement over current state
- **1** - Project affects a moderate percentage of targeted population or special needs population (peds, minorities) and / or is likely to provide moderate improvement over current state
- **2** - Project affects majority of targeted population or special needs population (peds, minorities) and likely to provides significant improvement over current state

Project Plan/Collaboration

- **0** - Barriers to completion not identified or adequately addressed and / or key stakeholders not identified or engaged
- **1** - Barriers to completion partially identified / addressed and / or only some key stakeholders identified / engaged
- **2** - Barriers to completion identified and addressed, key stakeholders identified and engaged

Cost/Benefit

- **0** - Anticipated expense cannot be justified on the basis of target population impact and / or timeline is clearly unrealistic (project) / insufficient priority (PC Proposal)
- **1** - Justification of anticipated cost questionable in relation to target population impact and / or timeline is somewhat unrealistic (project) / moderate priority (PC Proposal)
- **2** - Anticipated cost justifies the target population impact and timeline is realistic (project) / high priority (PC Proposal)

Include Specific Comments / Recommendations: