

**INTERIM REPORT of the  
OPTN/UNOS POLICY OVERSIGHT COMMITTEE**  
Meeting on October 10, 2012 in Chicago, Illinois

1. **Post Public Comment Review of Proposals** The Committee submitted one proposal for public comment during the spring 2012 cycle. The Committee reviewed the public comments and draft responses.

**Proposal to Rewrite the Data Release Policies**

The OPTN<sup>1</sup> Contractor has initiated a plain language rewrite of the OPTN policies and bylaws. The rewrite project is currently consolidating, reorganizing, and simplifying the language of the policies and bylaws. During the evaluation of the policies, it was noted that the data release policies contain outdated elements that require substantive changes. Since substantive changes are outside the scope of the plain language rewrite project, this proposal was distributed separately from the rewrite project. The current Policy 9 (Release of Information to the Public) and Policy 10 (Access to Data) were combined into one policy as outlined in this report. Below are several of the larger changes that are in the proposed policy language that was released for public comment. Several of these provisions were changed as a result of public comment.

- The proposed policy allows the OPTN Contractor to release more data than is currently released, but does not require its release in every case. In cases where there is disagreement between the OPTN Contractor and a requestor about whether data should be released, the Executive Director will make the final decision about release of confidential and personnel data, and the Policy Oversight Committee (POC) will make the decision about release of other OPTN data.
- The proposal sets requirements for the release of confidential information. These requirements are meant to protect confidential information and allow the release only in limited situations. Additionally, the policy defines confidential information (e.g., financial and personnel information).
- Under current policy, the OPTN Contractor may release by institution only the data elements specifically approved by the now-defunct OPTN Data Advisory Committee. Many of these fields are currently found on the OPTN website. The proposed language will allow the POC to maintain the list of data elements outside of policy.
- The proposal eliminates from policy language lists of data elements that can be released in special circumstances. Several lists of specific data elements that can be released under the current policy are not included in the new policy language because the language is being broadened, and future lists of releasable data elements will be approved by the POC. This approach will give the OPTN greater flexibility to modify the lists of releasable elements in the future.

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<sup>1</sup> Organ Procurement and Transplantation Network

- The process for release of person-identified data does not change. Person-identified OPTN data are given to researchers for bona fide research purposes, but the OPTN Contractor only fulfills requests that are *approved by HRSA* because the OPTN does not have the authority to release person-identified data to researchers.

This proposal was released for public comment between March 15, 2012, and June 15, 2012. The POC considered all public comments received on the proposal at its October 10, 2012, meeting. There was considerable concern about the potential misuse of OPTN data (e.g., use of center-level data for marketing efforts or by insurance companies) and potential risk to patient confidentiality (i.e., patients may be more easily identified if more institution-identified data are available to a wider audience). To address the concerns raised in the public comments, the POC considered each of the following issues:

- *Institution identifiers in patient-level data sets* – This is the information currently released in STAR (Standard Transplant Analysis and Research) files that contains center and OPO identifiers in the data sets only for research purposes. Currently, researchers are required to submit a concept paper stating why they need these data and sign a data use agreement promising not to publish in a way that identifies those institutions. The original proposal would eliminate these restrictions with the intent to allow for greater transparency and access to data. The institution identified data would be available to the public, not just to researchers, and the restriction on publishing by institution could be lifted. The restriction is currently in the data use agreement, but not in OPTN policy. Following discussion, the POC agreed to maintain the current process and allow an avenue for appeals as outlined in the proposed language. Additionally, if a researcher requests institution identified data, then the requester should provide a justification. The UNOS Research Department will periodically update the POC on the number of requests that are approved and denied.
- *OPTN data requests for summary information (e.g., listings, tables, etc.) by institution* - The OPTN receives many requests for summary data each month. These are analyses such as the number of patients with a certain diagnosis by OPTN region. Current policy allows the OPTN to release by institution only certain data elements that are on an approved list. For example, if a requester wants to know the diagnosis by transplant center that would be acceptable, but receiving information about which transplant center performs the most transplants on HIV positive patients would not be allowed under current policy. The original proposed policy change would remove such restrictions and allow the OPTN to release any data field by institution. The SRTR<sup>2</sup> noted that they also receive data requests and are not restricted by the list, so data are available through two mechanisms where one has restrictions and the other does not. HRSA noted that this proposal is a step in the right direction by reducing restrictions and that discussion with the SRTR regarding their process for releasing data should be reviewed in the future. Following public comment, there was agreement that a list of data fields that the OPTN Contractor may release as institution level summary data would be maintained by the POC.
- *Publication by institution* – The current data use agreement restricts requesters from publishing or presenting data that in any way identifies an institution. Currently the

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<sup>2</sup> Scientific Registry of Transplant Recipients

OPTN has no way of preventing the misuse of data and the only recourse is preventing offenders from having future access to data. There was a question raised about what constitutes a “publication.” Most medical professionals think of publication as peer-review literature where there is a step in the review process by journal experts. It was noted that currently the data use agreement states that the requester will not present or publish by institution. This is interpreted by UNOS staff as releasing the information outside the requester’s research group. Following additional discussion, the POC agreed to add policy language specifying that requesters provide an explanation for why they need institutional identifiers and agree not to publish or present in a way that identifies an institution.

- *Institutional Review Board (IRB) requirements* – The current policy does not require IRB approval to receive patient-level data sets. IRB approval is required for patient-identified data sets, which are covered by federal law. University researchers are usually required by their institution to have IRB approval for patient-level data, so this requirement should not cause a burden for those individuals. It could, however, be a burden to the public because they may not have access to an IRB. Additionally, some data for “quality or process improvement” might not require IRB approval because it is not being used for research purposes. There was a question about the process the OPTN Contractor uses to determine if a request is reasonable. Currently requests are reviewed by UNOS research staff before the data sets are released. It was noted that the proposed policy language does include an appeals process if requests are denied. It was noted that tracking the approval and denial of requests would be useful information for the POC to have in the future. Following discussion, the POC agreed that proof of IRB approval should be required for researchers, and anyone else requesting patient-level data will be required to submit a concept paper explaining the reasons for the request. Additionally, if an institution is requesting data for quality or process improvement, which some IRBs may not need to approve, then a concept paper is required. If there are concerns about a particular request, the POC will have the authority to make a decision. A subgroup of the POC will be created for this purpose.
- *Cell size limits* – During public comment, concerns were raised about patient confidentiality, and several commenters expressed a desire for cell size limits in publications. It was noted that even with patient-level data by institution there might be a way, especially for certain small subgroups of patients, for individual patients to be identified. The current OPTN policy does not restrict cell size in publications. It was noted that USRDS<sup>3</sup> and CMS<sup>4</sup> have cell size limits of ten, which might be acceptable for those data sets but not OPTN data. While cell limits could decrease the chances of patients being identified, it would also reduce the usefulness of the OPTN data to both researchers and the public. This includes certain data requests fulfilled by the OPTN as well as the data on the OPTN website. The POC agreed that placing limits on the cell size would not be the best way to address potential patient confidentiality issues. It was also noted that there are no cell size limits in the program-specific reports (PSRs), so maintaining consistency would be important.

HRSA noted that the data collected by the OPTN are essential to its function. The data are used for policy development and other vital functions. The OPTN also needs to ensure the

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<sup>3</sup> United States Renal Data System (USRDS)

<sup>4</sup> Centers for Medicare and Medicaid Services

transparency and availability of the data so that the public can have trust in the system. The Final Rule clearly states that the data should be available to researchers and the public for a variety of reasons, including assessing individual transplant program performance. HRSA noted that this proposal supports what is outlined in the Final Rule. If an individual seeks information about what transplant center has the most experience dealing with certain disease processes, then they should be able to get that information. As currently written, the policy does not allow the OPTN to provide that information. It was noted that the PSRs are a different issue than what this proposal addresses and are being addressed through a separate process. It was also noted that the PSRs are generated by a group of experts using comprehensive data without institutional bias, while wide-open access to data may lead to analyses that could be misleading for a variety of reasons.

While there was considerable concern about increasing the availability of data in the public comments, the POC agreed that modifications to the existing Data Use Agreement, requirements to submit a concept paper, and added IRB and publication requirements adequately address these concerns. The POC will submit the proposal to the Board of Directors for approval on November 12-13, 2012.

## **2. Geographical Disparities in Organ Allocation**

The issue of addressing geographical disparities in organ allocation is one of the key goals outlined in the OPTN Strategic Plan that was approved by the Board of Directors in June 2012. It was noted that this issue is currently being addressed within some of the organ allocation systems. The ultimate goal of addressing this issue is to identify and eventually come up with equitable allocation and distribution to best meets the needs of the patients. The first step could be to evaluate current allocation algorithms and determine if they are appropriate in their current format or perhaps could be enhanced to promote a broader distribution of organs in a measurable manner that is associated with an improved outcome. The POC acknowledged that each allocation system works differently and it is unlikely that one overarching set of principles will apply across all the systems. It was noted that the first step could be to endorse some broad ideas that will guide the organ-specific committees as they begin to address whether current allocation meets the desired goals or whether there needs to be some changes to the different allocation paradigms that might include broader geographic units.

Some of the comments from the POC members include:

- Remove the business aspect from the discussions and think more about how to better serve the patients. What might be best for a transplant center might not be what is best for the population as a whole, especially for those waiting for an organ. Economic factors can be a barrier to making changes that are acceptable to the transplant community.
- Consider separating OPOs from transplant centers because the recovery and distribution of organs does not have to be coupled.
- There are a number of issues to be considered including access to transplant, organ wastage, cold ischemia time, donation rates, etc.
- Impact of any change on patients throughout the country. For example the impact on patients in Montana versus those in New York City.

- The Pediatric Committee is pilot testing regional sharing for highly-sensitized patients so one approach could be to take smaller steps.
- Balancing cost versus outcomes.
- Geography is a significant concern to the Ethics Committee
- Potentially identify patient populations that are disadvantaged.
- Philosophical shift in thinking about the field of transplantation today

HRSA noted that this is an important issue to them because the issue of geography is explicitly stated in the Final Rule. It was noted that the Advisory Committee on Transplantation approved a recommendation in 2010 that states organ allocation should be evidence-based and not based on the arbitrary boundaries of DSAs or OPOs. Allocation systems should minimize this variation and HRSA is supportive of any approach to do so.

The SRTR noted that it will be very important to clearly define what will be optimized by any change. For example, reduction in waitlist deaths or lower MELD scores at transplant, increased access to organs, etc. The SRTR can then create a model that shows a system that appears to best achieve what you are trying to accomplish. The SRTR also noted that it will be important to identify what constraints you are not willing to sacrifice. For example, if you want to avoid shipping organs if it takes 8 hours or if you don't want to have worse outcomes. These are issues that can be addressed by the individual committees.

It was noted that it will be important to build in an education piece so the transplant community will be aware of what is going on and why we are doing this. It will be important to collaborate with committees and other individuals and organization as we work towards defining fairness. It was noted that this will not be an easy thing to do and it will generate considerable discussion. There was a suggestion to utilize the new education department at UNOS to assist the POC and other committees.

The POC discussed the importance of having a timeline for this important work. There was considerable discussion about the appropriate timeline with some members wanting something done within a year. It was acknowledged that this is a huge project and that the first step is to get the Board to endorse the POC recommendations and provide specific guidance. The POC also agreed that a reasonable milestone would be to have committees define fairness by June of 2013. It was noted that although the resolution directs the organ-specific committees to define fairness, they will be encouraged to seek input from other committees as they move forward in development of their recommendations.

The POC approved the following language to be considered by the Board. Committee vote: 16 in favor, 1 opposed, and 0 abstentions. The Executive Committee met on October 19, 2012, and recommended the resolution language be changed from "access to organ transplants" to "allocation of organs for transplant." The POC leadership agreed to this recommended change. The following is recommended for consideration by the Board:

**\*\* RESOLVED, that the Board of Directors approve the following position regarding geography in organ allocation:**

- The existing geographic disparity in allocation of organs for transplant is unacceptably high.
  - The Board directs the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013. The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represent patient outcome.
  - The Board requests that optimized systems utilizing overlapping versus non-overlapping geographic boundaries be compared, including using or disregarding current DSA boundaries in allocation.
3. **Policy Rewrite Project** The POC was provided with an update on the policy rewrite project. The project was distributed for public comment from July 2 to August 31, 2012. There was a considerable amount of comments received and UNOS staff is currently working through the comments. Since there will probably be significant changes to the policies based on the feedback, the proposal will need to be distributed for public comment again at a date yet to be determined.
4. **Multi-Organ Allocation** The POC continues to address multi-organ allocation. The Committee sent a memo to the organ-specific committees earlier in 2012 and will evaluate the feedback moving forward. The Committee also requested and received feedback from the Ethics Committee. The POC has a subcommittee that continues to work on this issue.
5. **Committee Projects** The POC briefly discussed the process for reviewing committee projects. This process was created in November 2010 by the Board of Directors because OPTN leadership recognized the need to oversee the work of the committees, set priorities, and establish work plans for each year. There were some modifications made to the process based on feedback from the initial review in 2011. This included changes to the new project form to better align with the POC scorecard as well as the creation of an ongoing project form and liaison profile form. Committee liaisons were instructed to work with their committee leadership to complete project forms for both new and ongoing committee projects in preparation for POC review. POC leadership and UNOS staff are currently working to improve the process in preparation for project reviews early in 2013.

Carl Berg, MD, Committee Chair  
Duke University Hospital

Robert A. Hunter, MPA  
UNOS Staff, Policy Analyst

### Attendance

<b>Name</b>	<b>Position</b>	<b>October 10, 2012</b>
Carl L. Berg, MD	Committee Chairman	X
Yolanda Becker, MD	Committee Vice-Chairman	X
Jonathan A. Fridell, MD	At Large	Phone
Kristie A. Lemmon, MBA	At Large	X
Richard N. Formica, MD	At Large	X
Timothy Shain	At Large	X
Eileen Brewer, MD	At Large	X
Meelie A. DebRoy, MD	At Large	X
David Mulligan, MD, FACS	At Large	X
Sean Van Slyck, MPA/HSA, CPTC	At Large	X
Sandra Taler, MD	At Large	X
Joseph Rogers, MD	At Large	X
Nancy Metzler	At Large	X
Dolly Tyan, PhD	At Large	X
Theresa Daly, MS, RN, FNP	At Large	X
Laurie Williams, RN, BSN, CPTC	At Large	X
Peter Reese, MD	At Large	Phone
Daniel Kaul, MD	At Large	X
Charles Mowll	At Large	
Stuart C. Sweet, MD, PhD	Ex-Officio	
Raelene Skerda, DPh, BPharm	HRSA	Phone
Robert Walsh	HRSA	X
Bertram L. Kasiske, MD, FACP	SRTR	X
Jon Snyder, PhD, MS	SRTR	X
Tabitha Leighton	SRTR	Phone
Robert Hunter	UNOS, Committee Liaison	X
James Alcorn	UNOS, Director of Policy	X
Jennifer Wainright, PhD	UNOS, Research Staff	X