Framework for Addressing Geographic Disparities in Organ Distribution

Policy Oversight Committee

Yolanda Becker, MD, Chair
Sue Dunn, RN, BSN, MBA, Vice Chair
November 11-12, 2013

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Board Resolution- November 2012

The Board approved the following resolution regarding geography in organ allocation:

1. *Existing geographic disparity in allocation is unacceptably high.*
2. *Organ-specific committees directed to define the measurement of fairness and any constraints for each organ system by June 30, 2013.*

Board Resolution (continued)

3. *The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represents patient outcome.*

4. *The Board requests that optimized systems using overlapping vs. non-overlapping geographic boundaries be compared (± current DSA boundaries in allocation).*

Overall Key Questions

- Should there ever be non-contiguous regions?
- Should DSAs be the first unit of distribution?
- Should regional review boards match the regions used for allocation or the regions for in-person meetings?
- Should we call these regions, districts, allocation units, zones, etc?

Overall Key Questions (continued)

- Should the metric of fairness be the same for all organ systems or can it be organ specific?
- Should there be multiple metrics of fairness per organ? If so, how do you prioritize the metrics?
- Are there metrics other than fairness that should be considered in this discussion? Utility?

Overall Key Questions (continued)

- How long should an allocation change be in place before the metrics can be assessed? Before another major or minor allocation change makes sense?
- What is the role of experimental methods in allocation, especially when only certain centers or areas can participate?

POC Recommendations – Oct 2013

On October 23, 2013, the POC continued its discussion of geographic disparities in organ allocation and offers the following guidance and specific recommendations:

POC Discussion Points-Regions

- Regions for organ allocation should be relatively contiguous.
- Define different allocation regions for different organs (kidney/liver/etc.).
- Define different regions for allocation and administrative purposes (DSA vs. UNOS region).

POC Discussion Points–Review Boards

- Organ-specific committees should determine the makeup of their own review boards.
- When review boards are established, it's more important to have consistency *within* the organ system than *across* organ systems.

POC Discussion Points–Metrics

- The metric for optimizing the allocation of organs will need to be organ specific and set by each organ-specific committee.
- Organ-specific committees should identify a primary metric of allocation, and also identify other secondary metrics for monitoring.
- Organ-specific metrics should be monitored for a set period (1yr?) so that the UNOS members can evaluate data to determine the metric's effectiveness.

POC Discussion Points–Metrics

- All metrics developed should also measure the impact on vulnerable populations such as children, the elderly, ethnic minorities, and highly sensitized candidates.
- Ethics Committee should continue to provide input to the organ-specific committees regarding the evaluation of a metric's justice and utility, and any other ethical issues it believes important to consider.

POC Discussion Points–Allocation

- Current allocation models use expanding tiers of geographic allocation, but all begin with allocation at the local (DSA or OPO) level.
- Allocation should not begin at the local level but should, instead, begin at least at the broader regional level.

POC Discussion Points

Other Considerations:

- The current variance system for testing experimental methods of allocation should continue.
- It will be *vitally important* to continuously reach out to all stakeholders in the transplant community during the process to provide education and build consensus within the community.

Resolution 11

RESOLVED, that the framework for how OPTN/UNOS Committees should address geographic disparities in organ distribution, as set forth in Resolution 11, is hereby approved, effective immediately.

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OPTN Policies Plain Language Rewrite

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Project Background

- Plain Language Policy Rewrite Project began in 2009.
- OPTN members, advisors, and UNOS staff contributed to the preliminary rewrite drafts.
- Input incorporated to ensure that plain language edits did not affect the meaning of the current policies.
- Plain language guidelines were followed as much as possible, as outlined at *www.plainlanguage.gov*.

Project Progression

- Initially went out for Public Comment in July 2012
- Comments sorted into four categories:
  1. Style/formatting issues
  2. Possible substantive changes to existing policy
  3. Clarification/plain language issues
  4. Parking lot issues

- Since then, staff worked to address each comment received

Collaboration

- OPTN/UNOS Committees (according to organ/subject)
- OPTN/UNOS Policy Oversight Committee Members
- Subject matter experts, including UNOS staff from:
  - Regional Administration
  - DEQ (Department of Evaluation and Quality)
  - Organ Center
  - Research
  - Instructional Innovations
  - Membership

Public Comment – Round 2

- August 2013
- Two live web presentations presented to Regions to encourage review and comment
- Comment collected using a focused on-line survey from the OPTN public comment website
- All public comment received is included in Exhibit D of the POC board report

New User-Friendly Features

- One searchable document
- Meaningful and consistent headings
- Consistent formatting
- Consistent headers and footers
- New numbering format
- Table of contents
- Increased use of tables & lists
- Page numbers
- Centrally located definitions
- Index
- Change history
- No More ~~Strikeouts~~ and Underlines

Public Comment

- OPTN/UNOS Committees provided comments
- Regions were asked to review and comment but did not vote
- AST, ASTS, AOPO, NATCO provided comment through Regional Administrators

Public Comment- Major Themes

- Requests for substantive changes that were added to the “parking lot”
- Some reviewers did not like the new allocation tables
- Minor typos
- Suggested re-phrasing for clarification
- Only a few inadvertent substantive changes were identified by reviewers

Post-Public Comment Changes

Changes made post-public comment include the following:

- Identified typos and formatting issues
- A few changes to language structure for clarification
- Minor corrections to allocation tables in Policies 6, 8, 9, and 10
- Identified substantive changes were corrected

Final Steps

- If approved, the policy rewrite will be effective on February 1, 2014
- The policies that will be posted on the OPTN website will be only policy that is approved *and* implemented
- No more strikeouts and underlines to decipher

Final Steps

Other mechanisms are being considered to display approved but not yet implemented policy language:

History

Policy 3.5: Allocation of Deceased Kidneys: 9/1[illegible]12/18/2007; 6/20/2008; 6/22/2010; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012

Policy 8: Allocation of Kidneys: Pending implementation (XX/XX/20XX), see *Board briefing paper, June 2013.*

Notes

- For membership and personnel requirements for kidney programs, see the *OPTN Bylaws, Appendix E*.
- For information on reporting candidate's unacceptable antigens to the OPTN Contractor, see *Policy 5.3.A: Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA).*
- For requirements to have a candidate's waiting time reinstated for immediate and permanent non function of a transplanted kidney, see *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.
- For allocation of multi-organs that include a kidney, see *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets*.

Resolution 12

RESOLVED, that the rewritten policies, as set forth in Exhibit B to the POC's report to the Board, are hereby approved, effective pending programming and notice to OPTN membership.

FURTHER RESOLVED, that the rewritten language of approved and currently implemented policies as set forth in Exhibit C to the POC's report to the Board, is hereby approved, effective February 1, 2014.

FURTHER RESOLVED, that the rewritten plain language version of the policies that are presented and approved by the Board at its meeting on November 11-12, 2013, as set forth in Exhibit D to the POC's report to the Board, are hereby approved, effective February 1, 2014.

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Plain Language Rewrite of Policies Approved at This Board Meeting (Resolution 12, part 3)

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New Board-approved Policy Changes

- Changes to policy language approved at this board meeting need to be reflected in the plain language rewrite
- This rewritten language is shown in Exhibit D of the POC board report
- The third part of Resolution 12 addresses this language

Amendment to Resolution 12

- On October 30, the OPO Committee made changes to the DCD proposal (Resolution 8) after recommendations from the Ethics Committee
- Voted 14-0 to accept changes
- This amendment incorporates these changes into the plain language rewrite of the policies

Questions?

Yolanda Becker, MD, Chair
Sue Dunn, RN, BSN, MBA, Vice Chair
Leigh A. Kades, MA, Policy Editor

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Amendment to Resolution 12

- Line 195 of Exhibit D to the POC report to the Board:

Strike:

Potential DCD donors are limited to patients whose medical treatment no longer offers a medical benefit as determined by the patient's primary healthcare provider and in consideration of any available advanced directive executed by the patient.

Insert:

Potential DCD donors are limited to patients whose medical treatment no longer offers a medical benefit to the patient as determined by the patient, the patient's authorized surrogate, or the patient's advance directive if applicable, in consultation with the healthcare team.

Amendment to Resolution 12

- Line 201 of Exhibit D to the POC report to the Board:

Strike:

Although the donation discussion should ideally occur after the decision to withdraw life-sustaining measures, the patient's healthcare team and the OPO should collaboratively develop a communication plan, with consideration for first person authorization laws and advanced directives, to determine on a case-by-case basis the most appropriate time to engage the legal next of kin in the donation discussions or to allow for family-initiated discussions regarding organ donation.

Insert:

Prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment.