

### III. Policy Proposals

#### *At-a-Glance*

- **Proposed Ohio Alternative Local Unit (ALU)**

- **Liver and Intestinal Organ Transplantation Committee**

Three Donation Service Areas (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a single, combined new Alternative Local Unit in the State of Ohio. There will be a single waiting list within the ALU for liver allocation. This will allow for better and more efficient allocation of organs to those on the waiting list with the most urgent need over a larger geographic area.

- **Affected Groups**

Directors of Organ Procurement, Executive Directors, Medical Directors, and Coordinators at LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network and in Region 10. Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Organ Candidates, Donor Family Members at the programs served by the sponsoring OPOs and within Region 10

- **Specific Requests for Comment**

The Liver Committee and sponsoring parties are seeking comments on the feasibility of this ALU, and any potential unintended consequences.

## **Proposed Ohio Alternative Local Unit (ALU)**

### **Liver and Intestinal Organ Transplantation Committee**

#### **Summary and Goals of the Proposal:**

Three Donation Service Areas (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a single, combined new Alternative Local Unit (ALU) in Ohio. For purposes of liver allocation, there will be a single waiting list within the ALU.

#### **Background and Significance of the Proposal:**

Since 1989, Ohio has had an approved alternative allocation system (AAS) that allocates livers locally, then to a statewide list, before allocating to the Region. After a systematic review of all AASs in 2008, which included several discussions of the AAS at the Liver, Executive, and Policy Oversight Committees, the Board voted in November 2009 to dissolve the AAS. The Secretary of Health and Human Services is reviewing the Board's decision at the request of the Ohio Solid Organ Transplant Consortium.

This proposed ALU would create a single local list for three of the four DSAs in Ohio. For purposes of liver allocation, there will be a single waiting list within the ALU. The three participating OPOs have agreed to systematically collect data regarding organ procurement, distribution, placement, quality and outcomes for review and analysis. Liver allocation would follow the standard national OPTN/UNOS Policy 3.6, with this combined unit defining 'local.'

#### *Advantages of the ALU*

The ALU will allow for better and more efficient allocation of organs to those on the waiting list with the most urgent need over a larger geographic area.

#### *Process for Approval*

Policy 3.4.8.1 (Application) states that "Applications to allocate organs using alternative point assignment systems or to distribute organs using sharing arrangements or ALUs are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Such applications are then reconsidered by the relevant Committee in light of public comment. Final applications to allocate organs locally using alternative point assignments or to distribute organs using sharing arrangements or ALUs must be presented to and approved by the Board of Directors before they can be implemented or used in organ allocation/distribution."

In February 2010, the Liver and Intestinal Organ Transplantation Committee approved that this ALU should be circulated for public comment by a vote of 15 in favor, 1, opposed, and 2 abstentions. The Committee cited the OPTN Final Rule's goal of "distributing organs over as broad a geographic area as feasible."<sup>1</sup> The AAS proposal was also reviewed and approved by the Policy Oversight Committee for distribution for public comment.

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<sup>1</sup> 42 CFR Part 121, see [http://optn.transplant.hrsa.gov/policiesAndBylaws/final\\_rule.asp](http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp)

Policy 3.4.8.1 also states that “In cases where unanimity cannot be achieved at the local level, applications to allocate organs using either an alternative point assignment system, sharing agreement or ALU must have approval of 75% of the Member OPOs and or transplant centers.” In this case, all participants are in agreement with the ALU<sup>2</sup>.

#### **Supporting Evidence and/or Modeling:**

There are no available data to support this proposal other than the generally accepted understanding that broader distribution provides better access to donor organs. The primary expected outcomes of the ALU include increased recovery rates, reduced number of liver discards, fewer deaths while on the waiting list and reduced time to transplantation once placed on the waiting list. These metrics will be measured before and after implementation and would be adjusted for donor and candidate characteristics. It is expected that this ALU will save lives by means of increased donor utilization and liver transplant rates.

#### **Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

This ALU would meet the OPTN strategic goals of achieving the best use of donated organs and equitable organ allocation, in order to reduce geographic variation in waiting list deaths and access to transplantation. As noted previously, this also addresses the goal stated in the Final Rule of “distributing organs over as broad a geographic area as feasible.”

#### **Plan for Evaluating the Proposal:**

The sponsors of this ALU hypothesize that creation of the ALU will lead to:

- Broader sharing of livers across three DSAs;
- Allocation of organs to patients with higher MELD/PELD scores; and
- Fewer deaths on the waiting list.

An evaluation will be conducted annually, using historical and modeled data, which would utilize the following data elements, currently collected by the OPTN:

- Livers recovered by type of donor (SCD, DCD, splits);
- Livers transplanted;
- Livers exported;
- Livers to research;
- Livers discarded;
- Adult deaths on waiting list by program and status of patient and MELD score at time of death;
- Pediatric deaths on waiting list by program and status of patient and PELD score at time of death; and
- Waiting time to transplant by MELD/PELD groupings.

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<sup>2</sup> [http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy\\_8.pdf](http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_8.pdf)

Proposed analyses of OPTN data include the following:

1. Hypothesis: Recovery rates of deceased donor livers in the new DSA will increase relative to the period preceding the ALU. This hypothesis will be tested using a multivariable logistic model adjusted for donor characteristics examining the likelihood of recovery adjusted for donor characteristics previously identified with recovery rates (e.g. age, race, donor history of disease, donor risk score, DCD). This analysis will also be stratified to DCD and higher risk donors based on the perception that the marginal effect of the ALU will be more evident in higher risk donor livers.
2. Hypothesis: Discard rates of recovered deceased donor livers in this DSA will decrease relative to the period preceding the ALU. This hypothesis will be tested using a multivariable logistic model adjusted for donor characteristics examining the likelihood of discard adjusted for donor characteristics previously identified (e.g. donor age, race, history of disease, donor risk score, DCD). This analysis will also be stratified to DCD and higher risk donors based on the perception that the effect of the ALU will be more pronounced in higher risk donor livers.
3. Hypothesis: Mortality rates will decrease on the liver transplant waiting list with the ALU implementation. This hypothesis will be tested based on time to patient death once placed on the waiting list in this DSA. Kaplan-Meier plots and multivariable Cox proportional hazard models will be used to test time to candidate death based on candidate risk factors at the time of listing (e.g. MELD score, age, primary diagnosis, race, gender.) This will be compared to the time period preceding implementation using a dummy variable in the model as an indicator for the period at which patients were listed. The analysis will be tested with and without incorporating removal from the waiting list as a censor to evaluate whether effects are evident independent of potential changes of patterns in de-listing patients. This analysis will also be stratified by transplant center to assess whether the ALU has had a similar impact in each center within the region and by adult and pediatric populations separately.
4. Hypothesis: Transplant rates will increase for patients once they are placed on the waiting list. This hypothesis will be tested based on models for time to transplantation, using both unadjusted Kaplan-Meier plots and multivariable Cox proportional hazard models comparing the time period prior to implementation to the time period following implementation. Cox models will be adjusted for relevant risk factors associated with mortality and time to transplant (e.g. blood type, PRA, age, MELD score, race, gender) and will be evaluated separately for each center. A sensitivity analysis will also be conducted with and without censoring of models for removal from the waiting list and separately for pediatric and adult populations.

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

Additional programming in UNet<sup>SM</sup> will be required to change the allocation algorithm for 3 Ohio DSAs into a single local unit. The Liver and Intestinal Organ Transplantation Committee will work with UNOS IT to implement this ALU.

**Communication and Education Plan:**

If approved this ALU will be communicated using the consolidated policy notice that is distributed after each Board meeting.

**Monitoring and Evaluation:**

The Department of Evaluation and Quality Allocation Analysis staff will monitor each allocation to ensure the available liver was allocated according to the match run sequence. If a member institution deviates from the policy, the Department of Evaluation and Quality may ask the center to clarify the allocation details. If the DEQ staff identify a potential violation of OPTN/UNOS policies or bylaws, they will forward all related information to the Membership and Professional Standards Committee for review and due process.