

## At-a-Glance

- **Proposal to Extend the “Share 15” Regional Distribution Policy to “Share 15 National”**
- **Affected/Proposed Policy:** Policy 3.6 - Adult Donor Liver Allocation Algorithm
- **Liver and Intestinal Organ Transplantation Committee**

The Committee is proposing an extension of the current “Share 15 Regional” policy so that deceased donor livers (age 18 and higher) would be offered to all candidates with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores.

- **Specific Requests for Comment:** The Committee asks the following:  
Do you support a policy that would offer deceased donor livers to all candidates in Status 1A/1B and with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores?
- **Number of Potential Candidates Affected:**  
Based on liver transplants performed in 2008-2010, there are an average of 259 livers that were transplanted in patients with a MELD/PELD score less than 15 (145 locally, 67 regionally, and 49 nationally). Of all candidates that were waiting for a liver during 2010, 14,780 (55.9% of total) were at some point listed with a MELD/PELD score of 15 or higher.
- **Compliance with OPTN Strategic Goals and Final Rule:**  
This meets the OPTN Strategic Goal of increasing access to transplants.
- **Affected Groups:**
  - Directors of Organ Procurement
  - OPO Executive Directors
  - OPO Medical Directors
  - OPO Coordinators
  - Transplant Administrators
  - Transplant Data Coordinators
  - Transplant Physicians/Surgeons
  - PR/Public Education Staff
  - Transplant Program Directors
  - Transplant Social Workers
  - Organ Recipients
  - Organ Candidates
  - Donor Family Members
  - General Public

## Proposal to Extend the “Share 15” Regional Distribution Policy to “Share 15 National”

**Affected/Proposed Policy:** Policy 3.6 - Adult Donor Liver Allocation Algorithm

### Liver and Intestinal Organ Transplantation Committee

#### Summary and Goals of the Proposal:

The Committee is proposing an extension of the current “Share 15 Regional” policy so that deceased donor livers (age 18 and higher) would be offered to all candidates in Status 1A and 1B and those with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores. Please refer to the algorithms on pages 4 and 7 for the sequence of allocation.

In a separate proposal, the Committee is proposing regional distribution of livers to candidates with MELD/PELD scores of 35 and higher. The Committee is asking for **separate comments and votes** for each proposal. However, the background, rationale, and much of the supporting evidence is common to both proposals, and is included in **Appendix A to this proposal**. Depending on public comment and subsequent Board consideration, the proposals could be incorporated into one algorithm.

#### Problem Statement:

Death rates for patients with a MELD score of 15 or greater are significantly higher than those with lower MELD scores. While this is especially true with MELD scores of 35 or higher, with a 33.7% risk of death at one year after listing, those in 15-34 range also have a much higher risk of death (17.4%) versus those with MELD scores less than 15 (8.8%), as shown in Figure 1. Currently, very few transplants are being performed in this cohort (Figure 2).

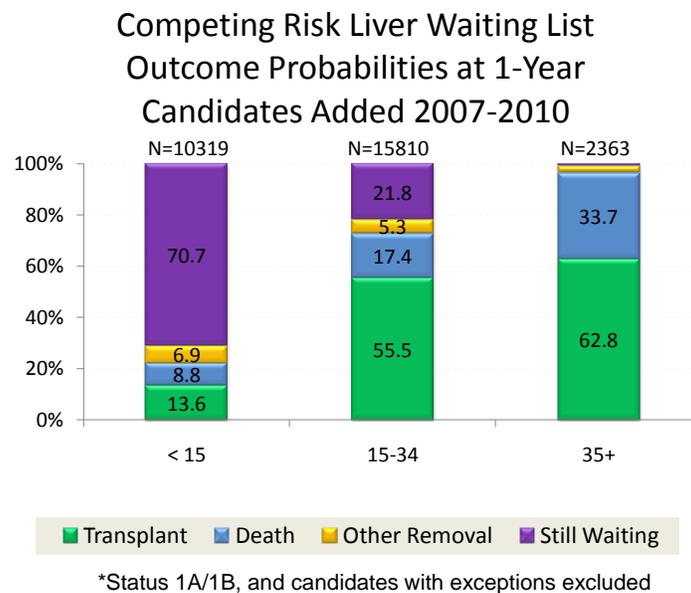
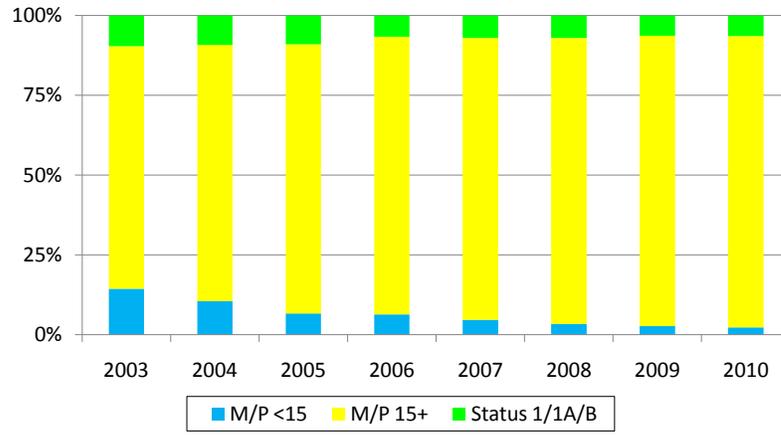


Figure 1: Source OPTN Data July 2011

## Deceased Donor Liver Transplants, 2003-2010 By Status/Score



**Figure 2: Source OPTN Data, July 2011**

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

Liver **allocation** has been based on the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores since 2002. This system prioritizes candidates based on mortality risk while awaiting liver transplantation and has been recognized as a major improvement in the way that candidates are prioritized for a liver transplant. **Distribution** refers to how donor livers are offered to the prioritized list of candidates, and has been based historically on the location of the transplant center relative to where the organ was procured.

The OPTN Final Rule<sup>1</sup>, effective March 2000, is a set of federal regulations that amplify the legal authority for the OPTN contained in the National Organ Transplant Act of 1984 (NOTA)<sup>2</sup>. The Final Rule governs organ allocation and OPTN policy development. The Final Rule specifies the bases upon which organ allocation policies may and may not be predicated, as well as performance goals for equitable organ allocation policies. One of the performance goals in the Final Rule is to distribute “organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency.” The Board has approved several changes to the liver **distribution** policy since the MELD/PELD allocation system was implemented in 2002 that are in compliance with this aspect of the Final Rule.

<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), hereafter referred to as the “Final Rule”

<sup>2</sup> National Organ Transplant Act (NOTA), 1984 Public Law 98-507, amended in 1988, 1990, and 2008 [http://www.unos.org/SharedContentDocuments/NOTA\\_as\\_amended\\_-\\_Jan\\_2008.pdf](http://www.unos.org/SharedContentDocuments/NOTA_as_amended_-_Jan_2008.pdf)

## History of Proposal Development

This proposal follows nearly two years of committee discussion, evidence gathering, and collaboration with the public and transplant community as described fully in **Appendix A**. Table 1 highlights the steps taken by the Committee to ensure that the community has been included in the policy development process.

**Table 1**

- Request for Information (RFI) Document and Survey, distributed in December 2009
  - 87 responses received, used to develop agenda and content for Forum
- Public Forum held in Atlanta in April 2010
  - 160 in attendance plus 70 via LiveMeeting
- Concept Paper and Survey, distributed December 2010 through February 2011
  - 227 responses
- Presentations at various transplant meetings (AASLD, ASTS Winter Symposium, ATC), in 2010 and 2011
- Updates to the OPTN/UNOS Board of Directors, 2010-2011
- Review of survey results at March 2011 Liver/Intestine committee meeting
- Review of SRTR modeling of National MELD 15 and Tiered Sharing at July 2011 Liver Committee meeting

## Supporting Evidence and/or Modeling

### Options Modeled and Results

During the March 2011 meeting, the Committee discussed feedback received to date. Of the 227 responses to the Concept Paper survey, **170 (75%) were in favor of the Share 15 National concept**. Based on all the feedback received from the efforts described above, the Committee voted to pursue further modeling of the Share 15 National (Share15N) concept. The Committee also asked the SRTR to model a regional distribution system for candidates with MELD/PELD scores of 35 and higher, which is described in a separate proposal. The SRTR modeled outcomes for these two potential options as separate changes as well as in combination. LSAM modeling outputs reviewed included

- Decrease in Total Deaths vs. Percent Shared;
- Decrease in Waiting List Deaths vs. Percent Shared;
- Decrease in Total Deaths vs. Median Distance;
- Death rate vs. Median Distance; and
- Percent of Liver Transplants Benefit from The Sharing Thresholds System Among All Transplants.

LSAM modeling demonstrated that Share15N (by itself) could reduce total deaths by 50 deaths per year, 40 of which would be waiting list deaths. Combined with a share for candidates with MELD/PELD scores greater than or equal to 35 would reduce deaths by 61 per year. Thus, these represent incremental changes (Figure 3).

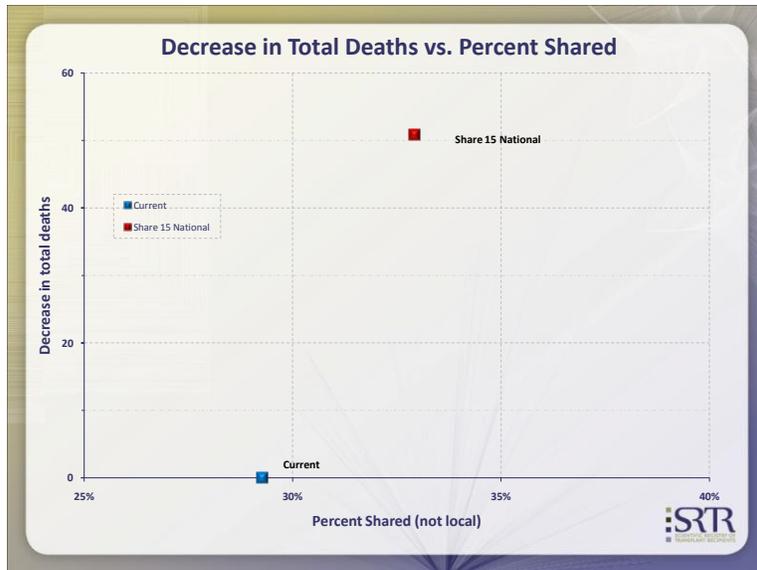


Figure 3 Source: SRTR LSAM Data, July 2011

It may also be noted that, since the Share 15 regional policy was implemented in 2005, the risk of death on the waiting list has decreased dramatically, as shown in Figure 4.

**Option Being Proposed: Share 15 National**

The Committee approved a motion to propose the “Share 15 national” concept for adult donor livers, including patients with MELD/PELD exceptions. This motion was approved by a vote of 23 in favor, 0 opposed, and 1 abstention. The Share15N concept is an extension of the current “Share 15” Regional policy (implemented in 2005).

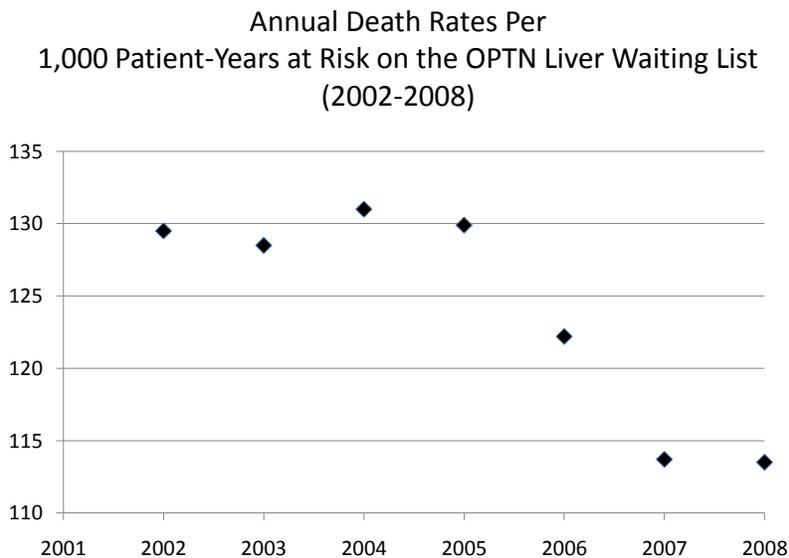
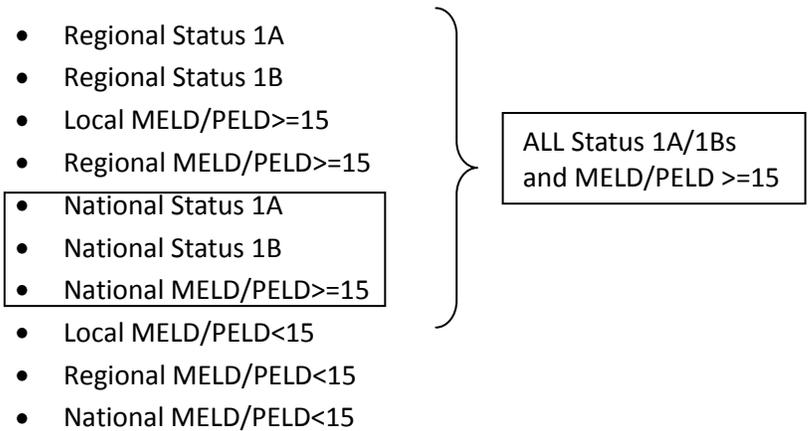


Figure 4 Source: SRTR Annual Report 2010

The proposed sequence for Share 15 National, for adult donors only, is as follows:



Thus, local and regional candidates with MELD/PELD scores of 15 or higher, and all Status 1 candidates, would have access to donor livers before being offered to candidates with MELD/PELD scores greater than 15 nationally.

### Potential Concerns

Based on all feedback received dating to 2009, the Committee has identified several concerns that may be raised with respect to this proposal:

- Some candidates with MELD/PELD scores less than 15 could be disadvantaged
- Longer distance traveled, increased cold ischemia time (CIT)
- Impact on local donation
- Concerns that the proposal does not “go far enough”

Data provided by the OPTN, SRTR, and several presentations and published papers are used to address most of these issues.

- Some candidates with MELD/PELD scores less than 15 could be disadvantaged. In the Concept Paper survey, the Committee sought feedback as to whether there could be a subset of candidates that could potentially be disadvantaged by a Share15N policy, and 47% expressed this concern. Some respondents were concerned that candidates with low serum could be adversely affected. One solution to this would be to add sodium to the MELD equation (MELD-Na), and asked that the SRTR provide data on the impact of such a modification. The Committee reviewed data showing that, of all candidates listed with a MELD score less than 15, those whose recalculated MELD-Na is in the 15-24 range have nearly double the rate of mortality than those with normal sodium levels. Thus, the disadvantage to these candidates could be mitigated by implementation of MELD-Na. The Committee unanimously approved a motion to review MELD-Na as a potential option in the future to address the issue of mortality in patients with hyponatremia and a calculated MELD score of less than 15.

- Longer distance traveled, increased cold ischemia time (CIT): Data provided by the SRTR indicate that the median CIT does not correlate well with distance, ranging from 6 hours for very short distances (less than 5 hours) to 7 hours for livers that traveled greater than 250 miles. LSAM modeling indicates that the Share15N proposal would increase the median distance organs travel from approximately 67 miles to 74 miles (Figure 5).

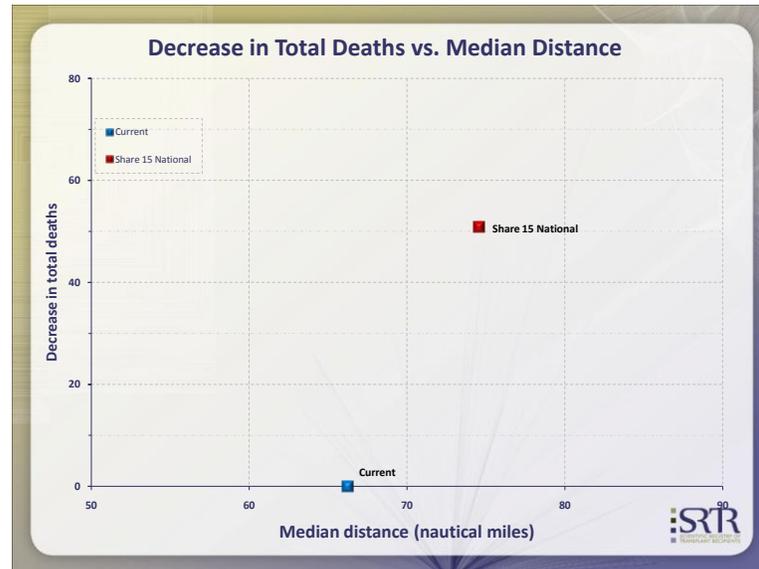


Figure 5 Source: SRTR LSAM Data, July 2011

- Impact on local donation: Volk, et al<sup>3</sup> reported that for a probability-based national sample of US adults, *“Only 10% of participants indicated that organs should stay in the community where they are donated, whereas the remainder of participants supported sharing of organs between communities.”*
- Concerns that the proposal does not “go far enough”: It must be recognized that some of the opposition to the proposals as presented in the Concept Document was from individuals that felt there should be even greater sharing of organs at the regional level. The Share15N proposal represents a small change to the Share15R algorithm that has already been tried successfully in all 11 regions since 2005.

### Expected Impact on Living Donors or Living Donation

This proposal is not expected to impact living donors or live donor liver transplantation.

### Expected Impact on Specific Patient Populations

This proposal is expected to impact critically ill liver candidates, directing livers to those most in need.

<sup>3</sup> Volk ML, Warren GJ, Anspach RR, Couper MP, Merion RM, Ubel PA. Foreigners traveling to the U.S. for transplantation may adversely affect organ donation: a national survey. Am J Transplant. 2010 Jun;10(6):1468-72. Epub 2010 May 10.

## **Other Impacts**

The Share 15 National may have the additional benefit of facilitating placement of organs already turned down at the local and regional level, thus reducing discards.

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

This meets the OPTN Strategic Goal of increasing access to transplants, specifically for the most urgent patients. In June 2010, the Board approved the following: RESOLVED, that the Liver and Intestinal Organ Transplantation Committee shall be charged with making recommendations to reduce geographic disparities in waiting list mortality.

## **Plan for Compliance with the Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2010**

The Conference Report associated with H.R. 3288 (the 2010 Transportation, Housing and Urban Development, and Related Agencies Appropriations Act) requires that the OPTN submit a report to the Committees on Appropriations of the House of Representatives and the Senate at least six months prior to implementation of any policy change affecting the distribution of livers. This report must describe the potential impact of these changes, using a list of nine metrics outlined in the report, as well as a description of all public comments received and the plan for addressing those comments. The report also stipulates that such changes must be tested first in demonstrations before nationwide implementation, and that changes should be made in “an incremental manner, reflecting the accumulation and analysis of data on the impact of policy changes.” The OPTN intends to comply with these requests.

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

The hypothesis guiding the proposal is that greater access to organs for sicker candidates will decrease their waiting list mortality, without a demonstrable increase in mortality for other candidates, due to the small number of candidates involved. The committee will examine waiting list mortality rates pre- and post-policy implementation for adult liver candidates. Data will be reviewed every 6 months post-implementation.

Data to be reviewed will include:

1. Waiting list mortality by MELD score
2. Post-transplant patient and graft survival
3. Percent shared between OPOs
4. Percent shared nationally

## **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 modify the allocation algorithm for adult deceased donor livers. The Liver and Intestinal Organ Transplantation Committee will work with UNOS IT to implement this policy.

**Communication/Education Plan:**

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice following Board Approval	Liver candidates, transplant surgeons, transplant physicians, transplant coordinators, OPO procurement coordinators, OPO executive directors, OPO medical directors, OPO PR/public education staff, public, transplant administrators, and transplant public relations/public education staff	Blast e-mail, OPTN and UNOS websites	1 month after Board approval
System Notice upon implementation	All UNet <sup>SM</sup> Users	Blast e-mail, UNet <sup>SM</sup> notice	TBD

**Monitoring and Evaluation**

The Department of Evaluation and Quality (DEQ) staff reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet<sup>SM</sup> system. Staff examines any instance where the match run was not followed and makes a written inquiry into any allocations that do not follow the match run sequence.

**Policy or Bylaw Proposal:**

Adult Donor Liver Allocation Algorithm

**Combined Local and Regional**

1. Status 1A candidates in descending point order
2. Status 1B candidates in descending order

**Local**

3. Candidates with MELD/PELD Scores  $\geq 15$  in descending order of mortality risk scores (probability of candidate death)

**Regional**

4. Candidates with MELD/PELD Scores  $\geq 15$  in descending order of mortality risk scores (probability of candidate death)

**National**

5. Status 1A candidates in descending point order
6. Status 1B candidates in descending point order
7. Candidates with MELD/PELD Scores  $\geq 15$  in descending order of mortality risk scores (probability of candidate death)

**Local**

8. 5- Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)

**Regional**

9. 6- Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)

**National**

- ~~7. Status 1A candidates in descending point order~~
- ~~8. Status 1B candidates in descending point order~~
- ~~10. All other candidates in descending order of mortality risk scores (probability of candidate death)~~  
Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)