

## At-a-Glance

- **Proposal to create regional distribution of livers for Status 1 liver candidates**
- **Policy affected: Policy 3.6 (Allocation of Livers)**
- **Liver and Intestinal Organ Transplantation Committee**
- In 2007, the OPTN asked the Liver and Intestinal Organ Transplantation Committee to identify strategies to increase broader geographic distribution of livers to reduce waitlist mortality. *The Liver-Intestine Committee proposes to eliminate “local” from the adult donor liver allocation algorithm thus making “regional” the first level of allocation for Status 1A and 1B candidates.* This modification should give the sickest candidates better access to livers. . This modification is expected to reduce waiting list mortality for Status 1 liver candidates by making more suitable organs available.

*This proposal is similar to the proposal to create regional distribution of livers for MELD/PELD candidates. That proposal is being circulated separately.*

- **Affected groups**  
Pediatric and adult 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
- **Specific requests for comment**  
Transplant coordinators and physicians should consider the following questions when reviewing this proposal:
  - Does expanding the first level of allocation to a regional level have the potential to reduce the total number of Status 1 waiting list deaths?
  - Do you foresee any significant negative impact resulting from the predicted moderate increase in average distance travelled?

All readers should consider and comment on the entire proposal. Please do not feel limited to the questions above. Those questions highlight key issues within the proposal that may specifically interest some readers.

## Proposal to create regional distribution of livers for Status 1 liver candidates

Policy affected: Policy 3.6 (Allocation of Livers)

### Liver and Intestinal Organ Transplantation Committee

#### Summary and Goals of the Proposal:

This proposal will create regional distribution of livers for Status 1 candidates. This proposal should give the most urgent candidates waiting for a liver transplant more access to organs.

#### Background and Significance of Proposal:

OPTN/UNOS liver allocation policy has always granted priority to those candidates in highest urgent need of a liver transplant. A synopsis of changes to the definitions used to identify medically urgent patients is outlined in Table 1 below. Changes implemented in August 2005 were designed to ensure that the priority assigned to Status 1 candidates is reserved for those candidates with the most immediate need for a liver transplant. These changes more stringently defined Status 1 (A and B) for adult and pediatric liver transplant candidates. With these definitions in place, the Liver Committee began to investigate broader geographic distribution for the sickest candidates as the next logical step in the evolution of the liver allocation policy. This is consistent with the OPTN Final Rule<sup>1</sup>, which states that one of the goals of developing equitable allocation policy is to distribute “organs over as broad a geographic area as feasible.” The Committee has already modified the liver allocation policy address this goal. These changes included distributing pediatric livers regionally, “Share 15” and broader distribution for combined liver-intestine candidates. Several regions (1, 9, and 10) have had alternative allocation systems with regional distribution for Status 1 candidates in place for years.

**Table 1. Chronology of Changes to Urgent Status for Liver Candidates**

|                  |  |
|------------------|--|
| <b>1987-1991</b> | “UNOS/STAT” assigned to candidates expected to live less than 24 hours without a transplant  |
| <b>1991</b>      | UNOS/STAT replaced by Status 4, which included both chronic and acute candidates with a life expectancy without transplant of 7 days or less.                            |
| <b>1994</b>      | Renamed as Status 1 in 1994 for consistency with other policies  |
| <b>1997</b>      | Status 1 (for adult candidates) revised to include only those candidates with acute liver failure with a life expectancy without a liver transplant of less than 7 days. |
| <b>1998</b>      | Status 1 definition for pediatric candidates further refined, such that at least one of ten specific clinical conditions must be met                                     |
| <b>1999</b>      | Regional Review Boards for review of Status 1 listings, facilitating institution of the policy for Regional distribution for Status 1 candidates.                        |
| <b>2002</b>      | Status 1 definitions maintained with implementation of MELD/PELD allocation system   |
| <b>2005</b>      | Status 1 redefined as Status 1A (acute liver failure, adults and pediatrics) and 1B (very ill pediatric candidates with chronic liver disease)                           |
| <b>2007</b>      | Combined Local/Regional Distribution for Pediatric Donors (awaiting implementation in UNET <sup>SM</sup> )   |

Throughout 2007, the Committee discussed the importance of identifying strategies to more broadly distribute livers to candidates listed in Status 1A/1B as well as those listed with MELD/PELD scores. Since the main goal is to the sickest patients from dying while on the waitlist, it was suggested that the

<sup>1</sup> 42 CFR §121.8 (a)

Committee should move forward with a “no local” allocation algorithm because it addresses the important issue of getting livers to the sickest patients within the regions. This includes Status 1A, Status 1B, and higher MELD/PELD candidates.

The Committee also considered distributing livers nationally for Status 1A candidates with fulminant hepatic failure (FHF). After discussions at the July 29, 2008 meeting, however, the Committee agreed distributing adult donor livers<sup>2</sup> regionally for all Status 1 candidates was a more moderate step.

*Motion: Proceed with the development of a proposal for regional sharing of livers for Status 1 candidates, which would eliminate local as the first tier of allocation. Committee Vote: 18 in favor, 2 opposed, and 1 abstention.*

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

As part of the policy development process, the Committee reviewed several analyses to assess the potential impact of regional distribution on Status 1 candidates and on the distance organs would travel.

#### Potential Impact on Status 1 candidates

The Committee requested data that would demonstrate the number of times a Status 1 candidate was transplanted locally when there was a Status 1 candidate in the region with more waiting time. OPTN data for Status 1A/1B allocations from 1/1/2007 – 12/31/2007 were included for this analysis. Match runs associated with each Status 1 transplant were analyzed to determine if there was a blood-type compatible or identical Status 1 candidate in the region with more waiting time than the local recipient.

In this group, there were 125 Status 1A transplants (33.8% of all Status 1A transplants) and 12 Status 1B transplants (18.2% of all Status 1B transplants) that occurred at the local level. During 19 (15.2%) of the 125 local Status 1A transplants, there was at least one ABO compatible/identical Status 1A candidate in the same region with more waiting time than the actual recipient. In total, there were 22 candidates with more waiting time in Status 1A than the recipient when these local Status 1A transplants occurred. Of these 22 Status 1A candidates that did not receive the offer, as of the time of the analysis:

- 14 eventually were transplanted (63.6%)
- 2 died prior to receiving a transplant (9.1%)
- 5 improved and were removed (22.7%)
- 1 was still waiting (not in Status 1) (4.6%)

During four (33.3%) of the 12 local Status 1B transplants, there was at least one ABO compatible/identical Status 1B candidate in the same region with more waiting time than the actual recipient. In total, there were 11 candidates with more waiting time in Status 1B than the recipient. Of these 11 Status 1B candidates that did not receive the offer, as of the time of the analysis:

- 5 eventually were transplanted (45.4%)
- 5 died or became too sick to transplant (45.4%)
- 1 was removed for other reasons (9.2%)

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<sup>2</sup> Note: The pediatric donor algorithms include combined local/regional allocation for some but not all groups of candidates; because these algorithms have been approved but not yet implemented, this proposal does not include a recommendation to remove “local” for all classifications of the pediatric donor allocation algorithm, but could be considered as an alternative proposal,

In summary, in 2007, there were 33 Status 1A/1B candidates that could have been offered an organ (based on blood type compatibility and waiting time in Status) that went to local Status 1A/1B candidates with less waiting time. Therefore, this proposal should have a potentially substantial impact on an urgent subset of liver transplant candidates.

#### Impact on Distance Traveled

The Committee understands concerns that centers may have regarding the increased distances that livers may travel with this proposed broader geographic distribution. SRTR modeling of full *national* distribution for Status 1As (which constitutes the larger proportion of Status 1 transplants) predicted that the median distance would decrease from 296 to 288 miles for regional allocations, and increase from 25 to 26 miles for local allocations.

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

The Committee's proposal will address two of the OPTN/UNOS September 2006-2007 Strategic Plan goals:

- Challenge 2 - Changing Allocation Principles
- Challenge 3 - Reduce Variation in Access to Transplantation

The Committee's goal of offering livers to the sickest candidates first over a wider geographic area than what is currently used meets provisions of the Final Rule as outlined in §121.8(b) (2) and (3).

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

The Liver and Intestinal Organ Transplantation Committees will review waiting list and transplant data to ensure that this change in allocation serves its intended purpose, without negatively impacting pre-transplant or post-transplant outcomes.

- **What questions/hypotheses are guiding the evaluation of the proposal?** Answers to these questions should help determine whether or not the proposal is meeting its intended goal(s).
  - To what extent have Status 1 waiting list death rates changed since policy implementation?
  - To what extent have Status 1 transplant rates changed since policy implementation?
  - To what extent has post-transplant survival changed since policy implementation?
- **Policy Performance Measures:** The following data will be provided to the Committee for the evaluation:
  - Status 1 waiting list death rates by age group and status before and after the policy change.
  - Status 1 transplant rates by age group and status before and after the policy change.
  - Number of regional transplants for Status 1 candidates outside the former "local" allocation area. Distribution of liver and liver-intestine transplants by donor and recipient age groups and status.
  - Post-transplant graft and patient survival by donor and recipient age groups and status. (Note: this will be provided when there is sufficient post-transplant follow-up information, i.e., after the policy is in place for 18 or 24 months)

#### ▪ **Time Line for Evaluation**

Data will be evaluated by the Committee every six months following implementation

**Additional Data Collection:**

No additional data collection in UNet<sup>SM</sup> will be required for this proposal.

**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 | Pediatric and adult 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:**

Review of Status 1A/1B Cases

Status 1A and 1B cases that do not meet criteria are retrospectively reviewed, initially by a subcommittee of the Liver Committee. The subcommittee makes recommendations to the full Committee as to whether the case is (1) not appropriate; or (2) does not meet criteria, but deserves special case exception. For the 141 Status 1A/1B cases reviewed by the Status 1A/1B subcommittee in 2008, 53 (38%) were determined to be inappropriate, and 88 (62%) did not meet criteria but deserved special case exception due to the particular circumstances of the case. Those found to be inappropriate by the Liver Committee received a letter from the Liver Committee; centers that repeatedly list candidates inappropriately repeat offenders are referred to the Membership and Professional Standards Committee (MPSC).

In June 2008, the Board approved modifications to policy 3.6.4.1 that will reinstate retrospective review of Status 1A/1B cases by the Regional Review Boards (RRB). Cases not resolved at the regional level will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the

MPSC for appropriate action. Until UNOS implements this new process, the current process of subcommittee review will continue.

### Allocation Monitoring

If this change is approved, the computer match system operated by the OPTN will be updated to reflect the allocation sequence. The computer match system operated by the OPTN:

- compares data entered into UNet<sup>sm</sup> for transplant candidates and organ donors;
- incorporates organ acceptance criteria specific to each candidate;
- eliminates candidates who are not suitable for the donor organ;
- ranks candidates according to approved OPTN policies; and
- produces a match run consisting of potential recipients in sequential order according to the priority defined by OPTN allocation policy.

OPOs are expected to allocate organs according to the match run generated by the OPTN computer match system. The UNOS Department of Evaluation and Quality (DEQ) monitors organ allocations to ensure organs are allocated according to the match run sequence. When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into UNet<sup>sm</sup> for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS MPSC for review.

### **Policy Proposal:**

The Liver and Intestinal Organ Transplantation Committees request your consideration and feedback on the recommended modifications to policies 3.6 (Allocation of Livers) as drafted below:

### **3.6 ALLOCATION OF LIVERS**

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old) will be allocated in the following sequence (adult donor liver allocation algorithm):

#### **Adult Donor Liver Allocation Algorithm**

##### ~~Local~~

- ~~1. Status 1A candidates in descending point order~~

##### **Combined Local and Regional**

- ~~2.~~ 1. Status 1A candidates in descending point

##### ~~Local~~

- ~~3. Status 1B candidates in descending order.~~

##### **Combined Local and Regional**

- ~~4.~~ 2. Status 1B candidates in descending point order

*Note: We are circulating a separate proposal that would eliminate local from the MELD/PELD algorithm.*

**Local**

~~5.~~ 3. Candidates with MELD/PELD Scores  $\geq 15$  in descending order of mortality risk scores (probability of candidate death)

**Regional**

~~6.~~ 4. Candidates with MELD/PELD Scores  $\geq 15$  in descending order of mortality risk scores (probability of candidate death)

**Local**

~~7.~~ 5. Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)

**Regional**

~~8.~~ 6. Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)

**National**

~~9.~~ 7. Status 1A candidates in descending point order

~~10.~~ 8. Status 1B candidates in descending point order

~~11.~~ 9. All other candidates in descending order of mortality risk scores (probability of candidate death)

**[No changes are being proposed to currently approved (but not implemented) pediatric allocation algorithms.]**