

At-a-Glance

- **Proposal to create regional distribution of livers for MELD/PELD 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 (Liver) Committee to identify strategies to increase broader distribution of livers to reduce waitlist mortality. *The Committee proposes to eliminate “local” from the adult donor liver allocation algorithm thus making “regional” the first level of allocation for MELD/PELD candidates.* This modification should provide the sickest candidates with better access to livers. This modification is expected to reduce waiting list mortality for MELD/PELD candidates by making more suitable organs available.

This proposal is similar to the proposal to create regional distribution of livers for Status 1 candidate. We are circulating that proposal 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,, 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:
 - Do you foresee any significant negative impact on:
 - Costs?
 - Travel Time
 - Other Factors?

All readers should consider and comment on the entire proposal. Please do not feel limited to the questions above. They are meant only to point out key issues within the proposal that may specifically interest some readers.

Proposal to create regional distribution of livers for MELD/PELD 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 MELD/PELD candidates. This proposal should provide those in most need of a liver transplant greater access to organs.

Background and Significance of Proposal:

The OPTN/UNOS continuously assesses national policy for allocating livers and updates the policy as appropriate. Perhaps one of the most significant changes was the move from the status-based system used from 1987-2002 to the MELD/PELD allocation system implemented in February 2002. During the last six years, the Liver and Intestinal Organ Transplantation (Liver) Committee has monitored the impact of the MELD/PELD system, and has made changes to the allocation system. In January 2005, UNOS implemented the "Share 15" policy, which allocates livers to candidates with a MELD/PELD score of 15 or higher locally then regionally before allocating to candidates with a lower MELD/PELD score. Following Status 1A/1B candidates, adult donor livers are allocated first to candidates with MELD/PELD scores of 15 or higher locally, then regionally, before allocating to candidates with a lower MELD score.

As one of its Annual Goals for 2007-2008, the Liver Committee was told to identify strategies to more broadly distribute livers in order to reduce deaths on the waiting list and direct organs to the sickest patients first. The OPTN Final Rule¹ states that one of the goals of developing equitable allocation policy is to distribute "organs over as broad a geographic area as feasible." The underlying purpose of this goal is "achieve sharing of organs broad enough to achieve medically effective results for patients, especially by providing organs for patients with greatest medical urgency who are appropriate candidates for transplantation." During the November 28, 2007, meeting, the Committee discussed the importance of identifying strategies to increase broader distribution and formed a subcommittee to specifically discuss some initiatives. If the main goal is to decrease waitlist mortality for the sickest patients, then a "no local" algorithm would address the important issue of getting livers to the sickest patients (Status 1A, Status 1B, and higher MELD/PELD candidate) within the regions. In fact, the OPTN/UNOS Board of Directors already approved combined local/regional distribution for pediatric donors by².

As a starting point, the Committee reviewed data requested during the development of the Region 8 alternative allocation system (AAS) proposal to see if it was applicable to the national allocation system. Region 8's AAS, implemented in 2007, provides for regional distribution of livers for MELD/PELD scores of 29 or greater. The Share 15 policy change was based on analyses demonstrating that there is a benefit from liver transplantation for candidates with MELD/PELD score of 15 or higher. However, there are no analyses that demonstrate a similar breakpoint for higher MELD/PELD scores, and Committee members acknowledged that the MELD/PELD of 29 score used in Region 8 was somewhat

¹ 42 CFR §121.8 (a)

² 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.

arbitrary. Committee members felt that a more evidence-based approach would be to share for all MELD/PELD scores.

An analysis of regional distribution across all 11 regions for all MELD scores indicated that the number of total deaths was predicted to decrease from 2723 to 2646. The percentage of transplants performed using organs procured from donors outside the local DSA but within the region would increase in each region, but the proportion of the total transplants performed in each region would not change substantially. While one concern about regional distribution is whether or not organs will travel greater distances, the data indicated that regional distribution would increase the average distance traveled only slightly (68 miles).

Based on these analyses, which are further described below, the Committee agreed to develop a proposal for regional distribution for MELD/PELD scores which would eliminate local as the first tier of allocation. A separate proposal will be submitted to create regional distribution for Status 1 candidates.

Motion: Proceed with the development of a proposal for regional sharing (all MELD/PELD scores), 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:

The committee used results of the SRTR's Liver Simulated Allocation Model (LSAM) to evaluate the impact of regional distribution across all regions. The results of the analysis showed the following (see Exhibit 1 for additional details):

- The number of transplants to candidates with MELD/PELD 25+ is predicted to increase from 2,296 transplants under the current rules to 2,496 transplants under a regional distribution system (200 additional transplants). Increases in the number of transplants to these high MELD/PELD candidates are observed in every region.
- Transplants in the MELD/PELD 15-24 category are predicted to decrease from 3,255 under current rules to 3,009 under a regional distribution system (246 fewer transplants). The percentage of regional transplants is predicted to increase from 24% to 47%, with a corresponding decrease in local transplants from 70% to 40%.
- Total deaths are expected to be 1.6% (n=42) lower in the first year following implementation.
- As expected under a system involving more extensive distribution, the median distance between the donor center and the transplant center is predicted to increase in each of the 11 regions. The overall increase in median distance was predicted to be 68 miles.

While there may be concerns about the shift in livers transplanted out of the local area, you should note that the shift to "Share 15" did not reduce the number of local transplants, as was originally predicted by the LSAM model. As reported by Pomfret, et al in 2007:³

"Most interestingly, despite major changes in the MELD scores of recipients and marked reductions in the number of low-MELD transplants being performed after the implementation of the new policy, there was almost no change in the number of livers shared outside the local DSA

³Pomfret EA, Fryer JP, Sima CS, Lake JR, Merion RM. Liver and Intestine Transplantation in the United States, 1996–2005. *American Journal of Transplantation* 2007; 7 (Part 2): 1376–1389

under the new system. Specifically, there was no change in the proportion of locally transplanted or regionally transplanted livers. This suggests that the policy goals were realized through behavioral changes at the local level. Decisions at the local DSA level to accept donor livers for high-MELD candidates that would have previously been reserved for lower-MELD candidates (by turning down such offers for the higher MELD candidates) may explain this phenomenon.”

The Committee felt that focusing on reducing waiting list deaths rather than the location of the transplant relative to the donor favored a more patient-based policy and was more in line with the requirements of the OPTN Final Rule.

Please note an important caveat with respect to the predicted increase in distance traveled. The LSAM model does not incorporate distance into its organ acceptance rate model. Thus, in large regions or regions with “unique geography,” such as Region 6, these estimates will be inflated. Further, based on SRTR analyses of the cold ischemia time (CIT) for livers transplanted locally versus regionally (Exhibit 1, Table 5), the increase in median CIT is predicted to be one hour (6.5 hours for local versus 7.6 hours for regional shares).

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).
 - Have waiting list death rates changed after the policy change?
 - Have transplant rates changed after the policy change?
 - Has post-transplant survival changed since the policy was implemented?
- **Policy Performance Measures:**

The committee will review the following data:

- Waiting list death rates by MELD/PELD.
- Transplant rates
- Transplant rates by MELD/PELD
- Transplant rates by age group
- Number of regional transplants by MELD/PELD. 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 (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**

Once UNOS implements the policy change, the committee will evaluate the date every six months.

Additional Data Collection:

No additional data collection in UNetSM will be required for this proposal.

Expected Implementation Plan:

UNOS will have to reprogram UNetSM to modify the allocation algorithm for adult and pediatric donor livers. The Liver and Intestinal Organ Transplantation Committee will work with the UNOS IT Department to implement this policy if the board of directors approves it.

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 SM Users	Blast e-mail, UNet SM notice	TBD

Monitoring and Evaluation:

Audits of MELD/PELD Scores

During routine site surveys of liver programs, UNOS site surveyors review the laboratory values used to calculate the MELD/PELD scores for transplants. UNOS will continue this practice if the proposed policy is implemented. This will ensure that candidates listed with higher MELD/PELD scores are listed accurately.

Allocation Monitoring

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

- compares data entered into UNetsm 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 an OPO provides insufficient information, UNOS staff inquire in writing about any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff review a sample of allocations and validate data entered into UNetsm for donors in the review sample. UNOS staff forward potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (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):

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

[Note: A separate proposal recommending the elimination of "local" from the Status 1A and 1B allocation algorithm is also being circulated for public comment.]

Local

1. Status 1A candidates in descending point order

Regional

2. Status 1A candidates in descending point

Local

3. Status 1B candidates in descending order.

Regional

4. Status 1B candidates in descending point order

~~Local~~

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

Combined Local and Regional

~~6. 5. Candidates listed with a MELD/PELD Scores ≥ 15 in descending order of mortality risk scores (probability of candidate death)~~

Local

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

Regional

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

National

~~9. 6. Status 1A candidates in descending point order~~

~~10. 7. Status 1B candidates in descending point order~~

~~11. 8. All other candidates in descending order of mortality risk scores (probability of candidate death)~~

[No changes are proposed to current pediatric allocation algorithms]

Table 1. Number of Transplants by Region and MELD/PELD Category (averaged over 10 iterations)

Current		Regions										
	All	1	2	3	4	5	6	7	8	9	10	11
Status 1A	401	9	47	59	37	87	5	39	30	29	26	33
Status 1B	59	2	15	6	4	8	2	4	5	4	7	2
MELD/PELD 25+	2296	98	295	256	167	552	39	244	122	271	135	117
MELD/PELD15-24	3255	74	343	599	347	295	145	235	277	124	374	442
MELD/PELD < 15	316	11	31	36	27	14	15	26	30	14	39	73
Total	6327	194	731	956	582	956	206	548	464	442	581	667

Regional Distribution		Regions										
	All	1	2	3	4	5	6	7	8	9	10	11
Status 1A	395	8	47	64	34	86	5	37	27	29	26	32
Status 1B	56	2	15	6	3	8	2	4	4	4	6	2
MELD/PELD 25+	2496	101	332	272	182	614	43	266	135	275	147	129
MELD/PELD15-24	3009	68	299	566	332	235	142	216	262	120	354	415
MELD/PELD < 15	316	14	24	38	25	10	17	21	32	15	40	80
Total	6272	193	717	946	576	953	209	544	460	443	573	658

SRTR Note: We observed an increase in the overall number of transplants for candidates with MELD/PELD scores of 25+ from 2,296 transplants under the current rules to 2,496 transplants under a regional distribution system among all MELD/PELD scores. Increases in the number of transplants to these high MELD/PELD candidates are observed in every region. Transplants in the MELD/PELD 15-24 category are predicted to decrease from 3,255 under current rules to 3,009 under a regional distribution system. The number of transplants in the MELD/PELD < 15 category are not predicted to change. Table 1 shows the average number of transplants split out by region and MELD category. Note: Region 9 has always had regional distribution and therefore no differences were observed in the number of transplants between current and regional distribution.

Table 2. Number of Deaths by Region (averaged over 10 iterations)

Current												
	Regions											
	All	1	2	3	4	5	6	7	8	9	10	11
WL Deaths	1674	87	247	103	156	390	27	140	89	238	76	120
Post-Transplant Deaths	602	20	75	86	53	90	23	50	41	47	57	59
Post-Removal Deaths	411	23	49	48	26	103	17	35	17	35	29	29
Total	2686	130	372	238	235	583	66	225	147	320	163	208
Regional Distribution												
	Regions											
	All	1	2	3	4	5	6	7	8	9	10	11
WL Deaths	1622	87	243	98	146	374	24	135	86	236	76	118
Post-Transplant Deaths	624	19	77	90	55	95	22	51	43	52	63	58
Post-Removal Deaths	399	24	46	45	27	101	17	34	16	35	27	27
Total	2644	130	366	233	227	570	62	220	145	323	166	203

SRTR Note: Table 2 shows the average number of deaths split out by region and type of death (waitlist, post-transplant, or post-removal). Comparing the current allocation system to a system of regional distribution, overall deaths are expected to be 1.6% lower in the first year following implementation. The number of expected total deaths decreases in eight of eleven regions with the same number of expected total deaths in one region and minimally higher expected total deaths in two regions. The number of expected waitlist deaths decreases in nine of eleven regions with the same number of expected waitlist deaths in two regions.

Table 3. Distance Travelled by Region

	Current			Regional Distribution		
	10%	Median	90%	10%	Median	90%
All	2	78	481	4	146	587
Region 1	2	86	206	2	92	208
Region 2	0	57	253	3	81	266
Region 3	3	152	734	16	302	793
Region 4	0	101	468	0	196	467
Region 5	4	50	589	10	148	638
Region 6	2	61	150	1	2148	2423
Region 7	2	61	297	4	90	384
Region 8	2	128	555	3	223	721
Region 9	2	22	305	3	35	378
Region 10	0	78	231	3	123	262
Region 11	1	124	455	3	205	517

SRTR Note: Overall, the median distance traveled is predicted to increase from 78 under the current allocation rules to 146 under a regional distribution system among all MELD/PELD scores. Median distance traveled is predicted to increase in all regions (Table 3).

Table 4: Predicted Number and Percent of Transplants under Current Allocation System and Regional Distribution Allocation System*

	Current System	Regional Distribution System
All	6324 (100.0%)	6270 (100.0%)
Local	4451 (70.4%)	3020 (48.2%)
Regional	1572 (24.9%)	2945 (47.0%)
National	302 (4.8%)	305 (4.9%)

*Based on LSAM Runs from Data Request Presented to LI-IN Committee on 7/29/2008.

Table 5: Deceased Donor Liver Transplants 1/1/2005-12/31/2007

	Number of Transplants	N (%) with Missing CIT	Cold Ischemia Time		
			10%	Median	90%
All	18708	1972 (10.5%)	4.0	7.0	11.0
Local	12596	1312 (10.4%)	4.0	6.5	10.0
Regional	4486	438 (9.8%)	5.0	7.6	11.0
National	1626	222 (13.7%)	6.0	9.3	13.7