

# **Concept Document: Next Steps Toward Improving Liver Distribution**

**The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee is seeking feedback to improve the distribution of deceased donor livers.**

**SUBMITTED BY THE OPTN/UNOS LIVER AND INTESTINAL  
ORGAN TRANSPLANTATION COMMITTEE**

**Table of Contents**

I.	Purpose of the Document.....	3
II.	Background and Problem Statement.....	3
III.	Concepts Considered .....	5
IV.	Concepts Proposed for Further Consideration .....	6
	i. National Share MELD 15 .....	6
	ii. Tiered Regional Sharing & Sharing Threshold (ST) .....	7
	iii. Expedited Graft Placement .....	8
V.	Conclusions.....	8
VI.	Information Requested .....	9
VII.	Survey Questions .....	10
XIII.	Glossary.....	11
	Figures.....	12
	References .....	19

NOTE: The figures for this document appear at the end of the text, beginning on page 12, and the appendix is posted as separate documents on the web page.

# CONCEPT DOCUMENT: NEXT STEPS TOWARD IMPROVING LIVER DISTRIBUTION

## SUBMITTED BY THE OPTN/UNOS LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE

### Instructions

#### Key Dates

Release Date: January 4, 2011

Responses Due By: February 18, 2011 by 11:59pm (PST)

#### Issued by

United Network for Organ Sharing (UNOS) as the organization designated as the Organ Procurement and Transplantation Network (OPTN) by contract with the Health Resources and Services Administration (HRSA)

### I. Purpose of the Document

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (Liver Committee) is requesting further feedback from the transplant community regarding the next steps to consider for improving outcomes for patients awaiting liver transplantation (LT). Concepts discussed at a public forum held on April 12, 2010 form the basis of this document. Forum participants evaluated the current policies for deceased donor liver allocation and distribution in the US, as well as numerous potential modifications. This document summarizes the feedback from the forum, and highlights those concepts that appear to have sufficient community support to warrant further consideration.

### II. Background and Problem Statement

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 current system uses a local, regional, national algorithm. The local distribution unit is defined as the donation service area (DSA) of an organ procurement organization (OPO). After being offered to the sickest candidates (Status 1A/1B) regionally, deceased donor livers are offered locally, then regionally, to candidates with a MELD/PELD score of 15 or higher before being offered to candidates with lower MELD/PELD scores.

The average MELD/PELD score at which patients receive a transplant varies greatly, as seen in Fig 1. This variability exists within and between regions (Figs 2 and 3). Waiting list death rates are also variable (Fig 4) within and between regions (Figs 5). The Committee has been charged on

numerous occasions to investigate ways to reduce geographic variation. Most recently, the OPTN/UNOS Board approved the following motion in June 2010:

*\*\*\* RESOLVED, that the Liver and Intestinal Organ Transplantation Committee shall be charged with making recommendations to reduce geographic disparities in waitlist mortality.*

### Addressing the Charge: Past and Present

A policy that allocates livers regionally to critically ill (status 1A/B) patients, first implemented in 1999, has been shown to reduce waiting list mortality<sup>1,2</sup> and is well-accepted. Patients listed as a Status 1A/B must meet very strict criteria. If these criteria are not met, a patient can still be listed as a status 1, but the case is reviewed by the Liver Committee for potential referral to the Membership and Professional Standards Committee (MPSC).

The “Share 15” policy implemented in 2005 was intended to reduce waiting list deaths by directing livers to the patients who would most benefit. Analysis of national data showed that the vast majority of patients with a MELD score below 15 did not benefit from a liver transplant, and that the advantage of a transplant increases as the MELD score increases<sup>3</sup>. This research was the basis for the “Share 15” policy, which allocates livers first locally, then regionally, to candidates with MELD/PELD scores greater than 15 prior to local candidates with lower scores. The goal of this policy is to redirect deceased donor livers to sicker patients and away from less ill patients (MELD/PELD < 15) who, in general, will live longer without a transplant.

A proposal for regional distribution of livers to all patients ranked by their MELD/PELD score was distributed for public comment in the spring of 2009. A great deal of public comment was received in response to this proposal. Support for this policy was mixed and the Committee withdrew the proposal from Board consideration. However, a number of requests and ideas were put forward for the Committee to evaluate and assess in regards to improving the system. Subsequently, the OPTN/UNOS Board authorized a public forum to address issues related to liver allocation and distribution.

A nine-month period of robust modeling, evaluation and discussion led up to the forum. The OPTN Final Rule<sup>4</sup> laid the foundation for this process. One of the performance goals in the Final Rule, “distributing organs over as broad a geographic area as feasible....,” stimulated considerable discussion within the Forum Planning Committee. The concept of “feasibility” is an important one and should not be ignored. What is feasible to one center, or region, may not be for another. Factors pertaining to feasibility include, but are not limited to, cold ischemic time (CIT), use of air versus ground transportation, possible increased costs, and system inefficiencies. The concept of “feasibility” also leads to considerations about what is practical from an operational standpoint.

A request for information (RFI) was submitted to the public on December 18, 2009<sup>5</sup>. This document briefly summarized the history of and mechanisms for liver allocation and distribution, as well as some of the concepts that emerged from the spring 2009 public comment response. The RFI included a survey, which received 87 individual responses and many ideas for evaluation and possible change. These helped shape the agenda for the forum held in April 2010. The agenda included 12 topical presentations from members of the community and Committee members. The audience was polled throughout the day, repeating many of the questions included in the RFI

survey, and there was extensive time for audience participation and questions. The responses to these questions are provided in **Appendix A**. More than 160 individuals attended the forum, with at least 70 more joining through an internet broadcast. Feedback from the RFI and forum highlighted several areas of common ground and the potential for consensus-building moving forward.

### III. Concepts Considered

Concepts considered related to allocation included the use of **MELD-Na**<sup>6</sup>, use of a **refit MELD score**<sup>7</sup>, and **Transplant Benefit**<sup>8</sup>. As most forum participants indicated that the current *allocation* system does not need significant modification at this time, more emphasis was placed on evaluating potential modifications to the current *distribution* system. A number of distribution concepts were explored and modeled, to assess the potential impacts on waiting list deaths and distances organs would travel. The predominant theme of the feedback was advocacy for small, incremental and practical changes in distribution that would produce the greatest reduction in waiting list deaths while limiting the distances organs travel.

Expansion of the current regional “share 15” policy to a “**share 15 national**” received support. This expansion would direct deceased donor livers regionally, then nationally, to candidates with MELD/PELD score of 15 or higher before local candidates with MELD/PELD scores less than 15. One other type of distribution system studied in detail was **tiered MELD/PELD sharing**, whereby livers are first offered regionally to candidates with scores over a certain MELD/PELD threshold. Distribution via **concentric circles**, akin to the current thoracic organ distribution system, was evaluated. Circles defined by population density were also considered. Although the use of concentric circles has many positive aspects, such as eliminating arbitrary geographic boundaries, distribution based on donor location rather than the transplant center, and current use and acceptance by the thoracic organ community, this system would substantially change liver distribution and may not be “feasible” given the current sentiments, as concentric circles could not be classified as a small, incremental step. Based on modeling results using the Liver Simulated Allocation Model (LSAM), the distance organs traveled was less in the tiered algorithms compared to the concentric circle systems, and resulted in similar reductions in waiting list deaths.

One frequently-cited concern with tiered sharing is the possibility that donor livers could be shared across a moderate sized geographic area when the difference between a local patient and the non-local patient is 1 or 2 MELD/PELD points. Having livers “criss-cross” for patients with potentially comparable mortality risk is not practical. A concept termed risk-equivalent threshold (RET) was considered; this has been renamed as a “**Sharing Threshold**” (**ST**) to more accurately describe the concept. This would set some MELD/PELD differential between a local and non-local patient that would preclude a regional share.

RFI respondents and forum participants felt that the MELD/PELD allocation **system** was not broken, but that further refinement of MELD (such as incorporation of serum sodium) might be warranted. While transplant outcomes were felt to be important, **transplant benefit** (which incorporates pre-transplant mortality and post-transplant outcomes into one score), was thought to be premature for serious consideration. There was broad agreement that an **expedited liver placement policy** would help optimize utilization and would lead to more organs transplanted, reducing waiting list deaths.

#### IV. Concepts Proposed for Further Consideration

Feedback regarding **liver distribution** was generally polarized, with a majority of respondents feeling that geographic inequities should be addressed, but that any proposed changes should be small and incremental to avoid major disruptions to the current system. Costs to transplant centers were also felt to be an important consideration with any change. Given those *caveats*, several concepts seemed to have some support for further consideration.

##### i. National Share MELD 15

As stated above, the goal of the current “Share 15” policy is to redirect deceased donor livers to sicker patients and away from less ill patients (MELD/PELD < 15) who, in general, will live longer without a transplant. In 2009, 168 deceased donor livers (2.8% of total) were transplanted into candidates with a match<sup>1</sup> MELD/PELD score less than 15 (Table 1). On average these patients do not achieve a survival advantage with a liver transplant versus staying on the waiting list<sup>9</sup>.) Under a “Share 15 **National**” policy, livers would be offered nationally to candidates with MELD/PELD scores greater than 15 if no suitable candidate with a MELD/PELD of 15 or greater is found in the local or regional distribution areas (Table 2).

Table 1: Deceased Donor Liver Transplants, 2005-2009

Match MELD/PELD Score at transplant	2005 N=6121	2006 n =6363	2007 N=6228	2008 N=6070	2009 N=6101
<b>Status 1 (1,1A,1B)</b>	552 (9.0)	425 (6.7)	436 (7.0%)	424 (7.0)	385 (6.3)
<b>Exceptions</b>	1531 (25.0)	1625 (25.5)	1746 (28.0)	1923 (31.7)	1964 (32.2)
<b>&lt;15</b>	411 (6.7)	406 (6.4)	290 (4.7)	208 (3.4)	168 (2.8)
<b>15-24</b>	1961 (32.0)	2190 (34.4)	1968 (31.6)	1694 (27.9)	1620 (26.6)
<b>25+</b>	1664 (27.2)	1717 (27.0)	1788 (28.7)	1821 (30.0)	1963 (32.2)

An analysis of all active, non-Status 1 liver transplant candidates on the liver waiting list on January 31, 2009, showed mortality rates were 6.3%, 15.2% and 27.7% for those with MELD scores of <15, 15-24 and 25 or over<sup>10</sup> (Fig 6). Based on LSAM results, implementation of Share 15 National would result in a decrease of 25 deaths per year nationally when compared to the current policy. There was a small increase in the predicted median distance livers would travel, from 65 miles to 76 miles (Fig 7)<sup>11</sup>.

<sup>1</sup> Match MELD/PELD refers to the score used by the match run, which is either the calculated MELD/PELD score, or an approved exception score.

Table 2: Comparison of Distribution Algorithms for Adult Deceased Donor Livers:  
Current vs. National Share MELD 15

Current System	National 15
Regional Status 1A	Regional Status 1A
Regional Status 1B	Regional Status 1B
Local MELD/PELD $\geq$ 15	Local MELD/PELD $\geq$ 15
Regional MELD/PELD $\geq$ 15	Regional MELD/PELD $\geq$ 15
Local MELD/PELD $<$ 15	National Status 1A
Regional MELD/PELD $<$ 15	National Status 1B
National Status 1A	National MELD/PELD $\geq$ 15
National Status 1B	Local MELD/PELD $<$ 15
National MELD/PELD	Regional MELD/PELD $<$ 15
	National MELD/PELD $<$ 15

Questions to consider in your feedback:

1. Would you support a national share 15 policy?
2. Is there a subgroup of liver transplant candidates with low MELD/PELD scores who may be unduly disadvantaged by a National Share 15 policy?

## ii. Tiered Regional Sharing & Sharing Threshold (ST)

Tiered regional sharing at a calculated MELD/PELD threshold of 29 was implemented as an alternative allocation system (AAS) in Region 8 in 2007; the data from this experience was discussed during the forum. Modeling of tiered sharing at various thresholds for all regions was also presented. Analysis of the Region 8 “Share 29” AAS demonstrated that more livers were transplanted into higher MELD patients without an impact on post-transplant survival or overall wait list mortality. Models of tiered sharing with thresholds of 35, 32, 29, 25 and 22 were also presented, with the higher thresholds receiving the greatest support. The Region 8 experience, along with the modeling data at the various MELD thresholds, was considered in the context that there is similar waiting list mortality for patients with MELD $>$ 35 and Status 1A patients<sup>12</sup>

Given that there was general support for the tiered concept, and a desire for incremental changes, Regional Share 35 (or a lower threshold) is a potential path forward to facilitate transplant of the most urgent patients, reducing waiting list mortality with only modest increases in distance organs travel. This policy could be considered for adoption by itself or in conjunction with some **Sharing Threshold (ST)**. While there may be a statistical difference in wait list survival for patients with a MELD of 34 versus 35 (76% versus 79%), from a clinical standpoint this difference is likely negligible. For example, if the ST was set at 2 in a Regional Share 35 system, the first offers would be to regional Status 1 candidates, then back to the local OPO for any candidates of MELD 33 or higher. It would then go to the region for candidates with MELD $\geq$ 35, then back to the local OPO for candidates with MELD from 32 down to 15. While the concept of ST appears somewhat complex at first glance, it addresses concerns about multiple livers criss-crossing a region for patients with a similar risk of mortality.

Questions to consider in your feedback:

3. Do you think broader sharing for patients with high waiting list mortality is reasonable?
4. Would you support regional sharing for MELD 35(y/n), 32(y/n), 29(y/n)?
5. Should the ST concept be incorporated if tiered MELD sharing is endorsed?

### **iii. Expedited Graft Placement**

One topic brought up in the RFI feedback and further discussed at the forum was expedited organ placement. This happens currently, but without a formal, uniform set of rules that apply to all OPOs and transplant centers. Participants at the forum cited reducing discards of transplantable livers an obvious way to reduce waiting list deaths, given the most significant problem in organ allocation and distribution is the critical shortage of suitable donor livers. A subcommittee has been formed to consider potential mechanisms for expedited placement.

The Committee is interested in ideas from the community regarding optimal mechanisms for expedited organ placement. Feedback from OPOs would be particularly helpful. Concepts suggested included:

- Shortening the time required to respond to UNET<sup>SM</sup> offers from 60 minutes to 30 minutes; and
- Maintaining a list of centers (and/or patients within those centers similar to policy for expanded criteria donor (ECD) kidneys) that would be considered for expedited grafts.

Question to consider in your feedback:

6. Would you support a national policy for facilitated placement of donor livers that are not used locally or regionally?
7. What other mechanisms would reduce liver discards?

## **V. Conclusions**

The system for distribution of livers will never please everyone. The recent forum employed a deliberative, evidence-based process that allowed an opportunity for all stakeholders to participate. Hearing clearly that small, incremental change is the best path forward has given the Liver Committee some guidance regarding future potential policy recommendations. The Share 15/Share 35 (or 32, 29) Regional with ST algorithm would appear to decrease wait list deaths and minimize distance traveled as well as mitigate the criss-crossing of livers in a region. These changes could be enacted as one package incorporating all three proposals, or they could be considered one at a time. Individual regions could also apply for an alternative allocation system (AAS) to implement these changes with region-specific thresholds.

The Committee welcomes your feedback on these concepts as it continues to deliberate improvements to the liver allocation and distribution systems.



## **VI. Information Requested**

After reading this document, please take ten minutes to fill out a brief online survey related to the concepts just described. You will have the opportunity to submit other ideas, thoughts, concerns and concepts that you would like the Committee to consider.

Responses will be accepted until February 18, 2011. They may be submitted electronically using the following web-based survey:

**[Click here to give us your feedback](#)**

For those without internet access, responses to the survey on the next page of this document may be faxed to 804-782-7896 (attention: Liver Concept Paper Coordinator), or mailed to:

Attention: Liver Concept Paper Coordinator  
United Network for Organ Sharing  
700 N 4th Street  
Richmond, VA 23219

## **VII. Survey Questions**

### **Share 15 National Concept**

1. Would you support a national share 15 policy? (Yes/No, if No, explain)
2. Is there a subgroup of liver transplant candidates with low MELD/PELD scores who may be unduly disadvantaged by a National Share 15 policy? (Yes,/No; if Yes, explain)

### **Tiered Regional Sharing and Sharing Threshold**

3. Do you think broader sharing for patients with high waiting list mortality is reasonable? (Yes/No)
4. Would you support regional sharing for a MELD/PELD threshold of:
  - 35 (Yes/No)
  - 32 (Yes/No)
  - 29 (Yes/No)
5. Should the Sharing Threshold (ST) concept be incorporated if tiered MELD/PELD sharing is endorsed? Yes/No; if No, explain.

### **Expedited Graft Placement**

6. Would you support a national policy for facilitated placement of donor livers that are not used locally or regionally? (Yes/No, if No, explain)
7. What other mechanisms would reduce liver discards? (Open-ended)

### **XIII. Glossary**

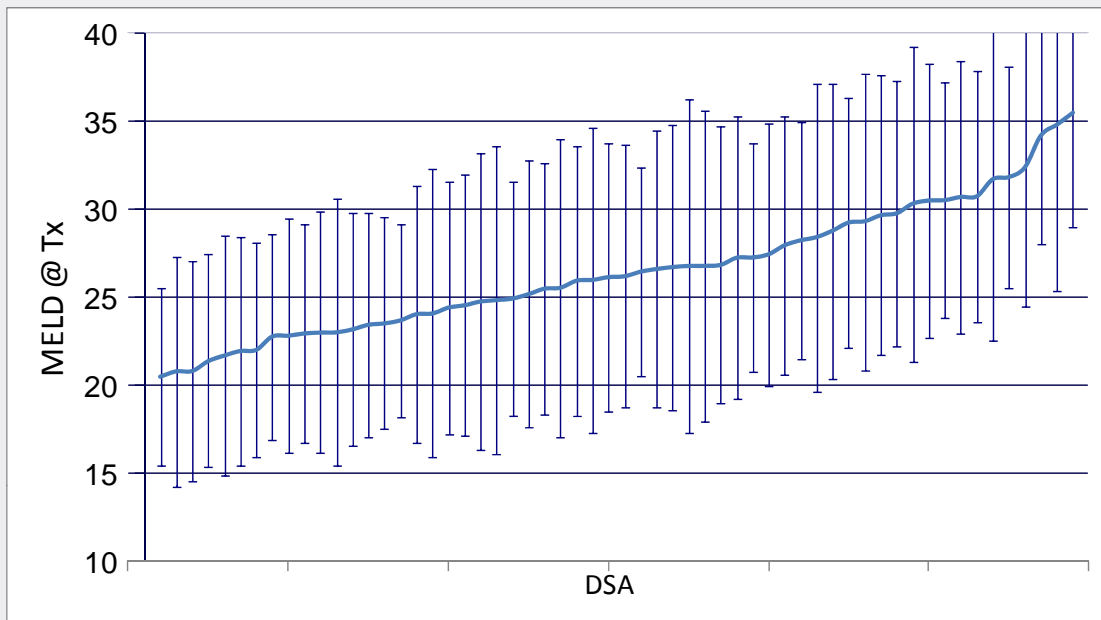
AAS	alternative allocation system
CIT	cold ischemia time
DSA	donation service area
ECD	expanded criteria donor
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration, an agency of the Department of Health and Human Services
LSAM	Liver Simulated Allocation Model
LT	liver transplantation
MELD	model for end-stage liver disease
MELD-Na	MELD with serum sodium
MPSC	Membership and Professional Standards Committee
OPO	organ procurement organization
OPTN	Organ Procurement and Transplantation Network
PELD	Pediatric End-stage Liver Disease
RFI	request for information
RT	risk threshold
SRTR	Scientific Registry of Transplant Recipients
UNOS	United Network for Organ Sharing

## References

---

- <sup>1</sup> Washburn K, Harper A, Klintmalm G, Goss J, Halff G. Regional sharing for adult status 1 candidates: Reduction in waitlist mortality. *Liver Transpl* 12: 470–474, 2006.
- <sup>2</sup> Humar A, Kwaja K, Glessing B, Larson E, Asolati M, Durand B, Lake J, Payne W. Regionwide sharing for status 1 liver patients – beneficial impact on waiting time and pre- and posttransplant survival. *Liver Transpl* 2004;10:661–665.
- <sup>3</sup> Merion RM, Schaubel DE, Dykstra DM, Freeman RB, Port FK, Wolfe RA. The survival benefit of liver transplantation. *Am J Transplant* 2005;2:307-313.
- <sup>4</sup> 42 CFR Part 121, see [http://optn.transplant.hrsa.gov/policiesAndBylaws/final\\_rule.asp](http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp)
- <sup>5</sup> [http://optn.transplant.hrsa.gov/SharedContentDocuments/LiverRFI\\_121809.pdf](http://optn.transplant.hrsa.gov/SharedContentDocuments/LiverRFI_121809.pdf)
- <sup>6</sup> Kim W, Biggins S, Kremers W, Wiesner R, Kamath P, Benson J, Edwards E, Therneau T. Hyponatremia and Mortality among Patients on the Liver-Transplant Waiting List. *N Engl J Med* 2008; 359:1018-1026
- <sup>7</sup> Sharma P, Schaubel D, Sima C, Merion R, Lok A. Re-weighting the model for end-stage liver disease score components. *Gastroenterology*. 2008 Nov;135(5):1575-81.
- <sup>8</sup> Schaubel D, Guideinger M, Biggins S, Kalbfleisch J, Pomfret E, Sharma P, Merion R. Survival *Am J Transplant*. 2009 Apr;9(4 Pt 2):970-81.
- <sup>9</sup> Merion R, Schaubel D, Dykstra D, Freeman R, Port F, Wolfe R. The survival benefit of liver transplantation. *Am J Transplant*. 2005 Feb;5(2):307-13.
- <sup>10</sup> Analysis provided to OPTN Liver and Intestinal Organ Transplantation Committee, July 13, 2010
- <sup>11</sup> Analysis provided to the OPTN Liver and Intestinal Organ Transplantation Committee, November 12, 2009
- <sup>12</sup> Sharma P, Schaubel DE, Gong Qi, Guidinger MK, Merion RM. End stage liver disease (ESLD) patients with high MELD have higher wait list mortality than Status-1 patients. *Am J Transplantation*, 2009, Vol 9, Suppl2, p 347.

**Figure 1**  
**Mean Match MELD @ Transplant**  
**Deceased Donor Liver Transplants, 2009**  
**Adults only, No Exceptions**

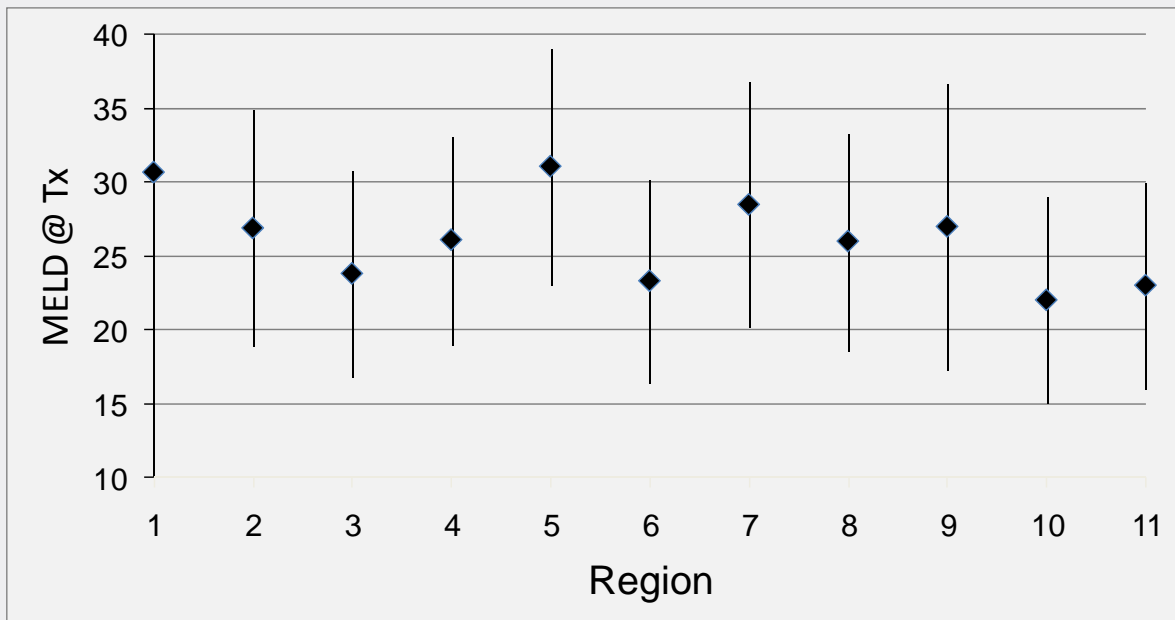


**OPTN**

Vertical Bars Represent 1 standard deviation from the mean

**UNOS** **DONATE LIFE**

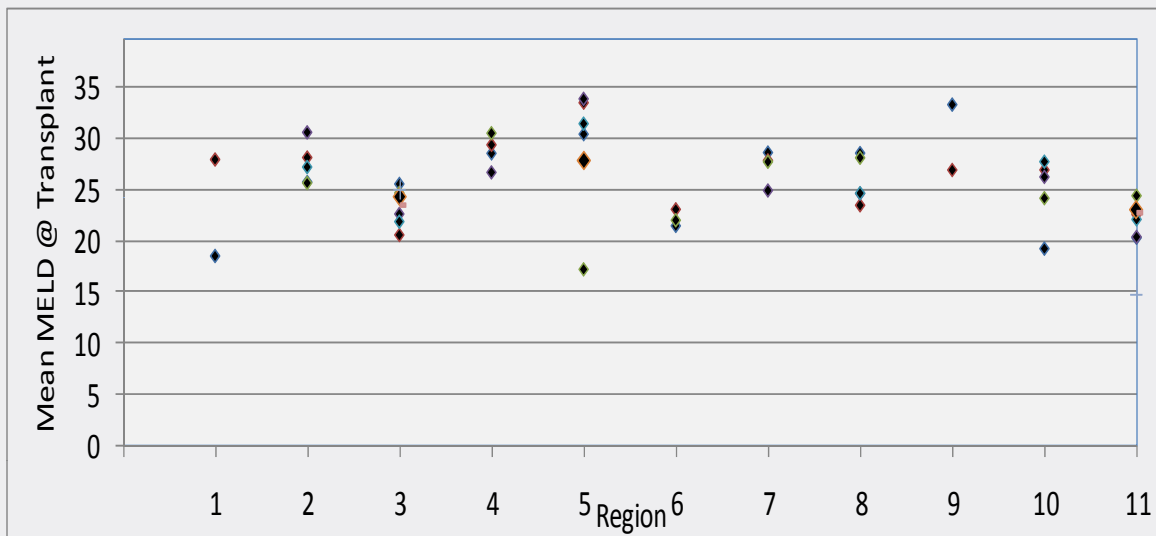
**Figure 2**  
**Mean Match MELD @ Transplant**  
**Deceased Donor Liver Transplants, 2009**  
**Adults only, No Exceptions**



Vertical Bars Represent 1 standard deviation from the mean



**Figure 3**  
**Mean Match MELD @ Transplant**  
**Deceased Donor Liver Transplants, 2009**  
**Adults only, No Exceptions**

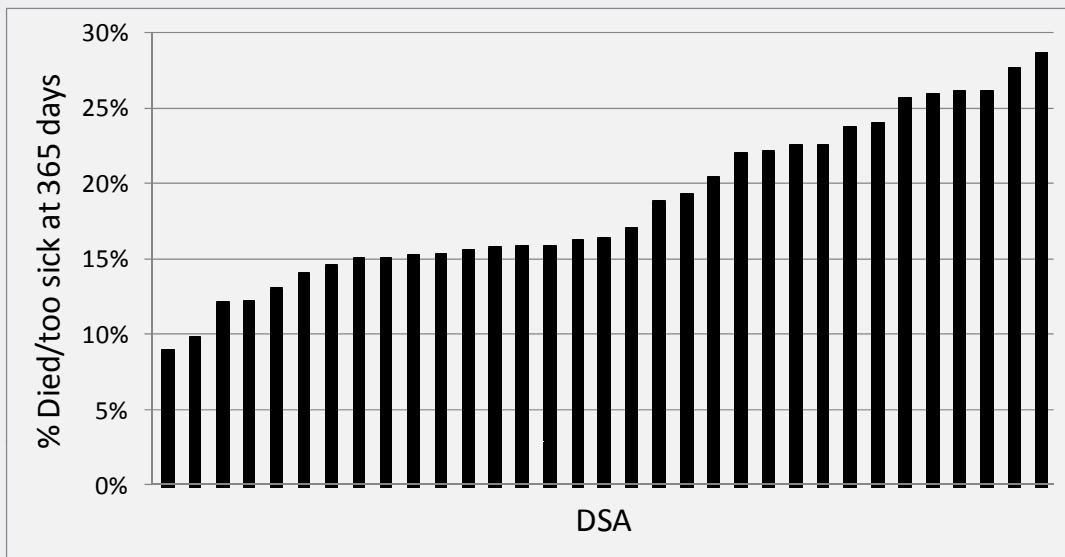


**OPTN**

**UNOS** DONATE LIFE

**Figure 4**  
**Death Rates\* @ 365 Days**  
**All Candidates Listed for a DD Liver Transplant**  
**1/1/2008-6/30/09**

Adults only, No Exceptions, Initial MELD  $\geq$  15, Candidates with and Initial Status of 1A/1B Excluded



\* Includes removals for too sick

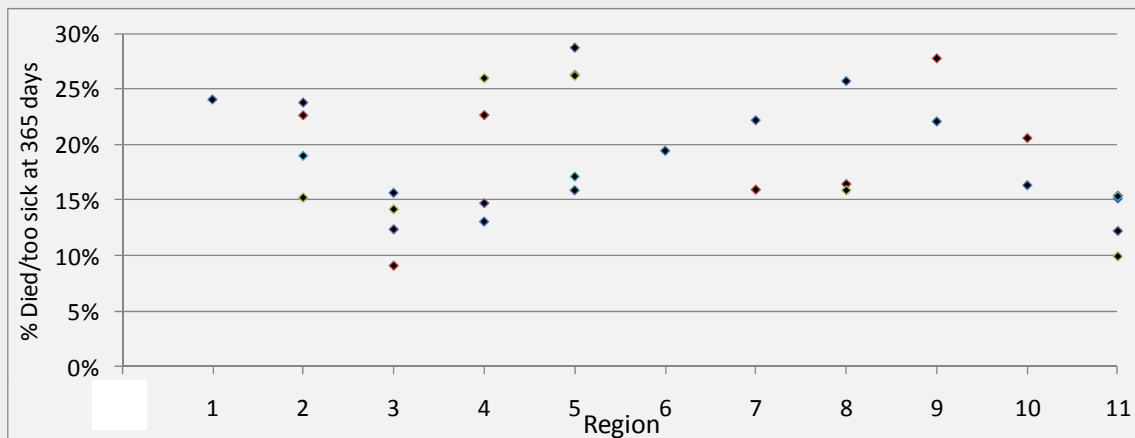
\*DSAs with less than 10 events not included





**Figure 5**  
**Death Rates\* @ 365 Days**  
**Candidates Listed for a DD Liver Transplant**  
**1/1/2008-6/30/09**  
**By DSA within Region**

Adults only, No Exceptions, Initial MELD $\geq$ 15, Candidates with an Initial Status of 1A/1B Excluded



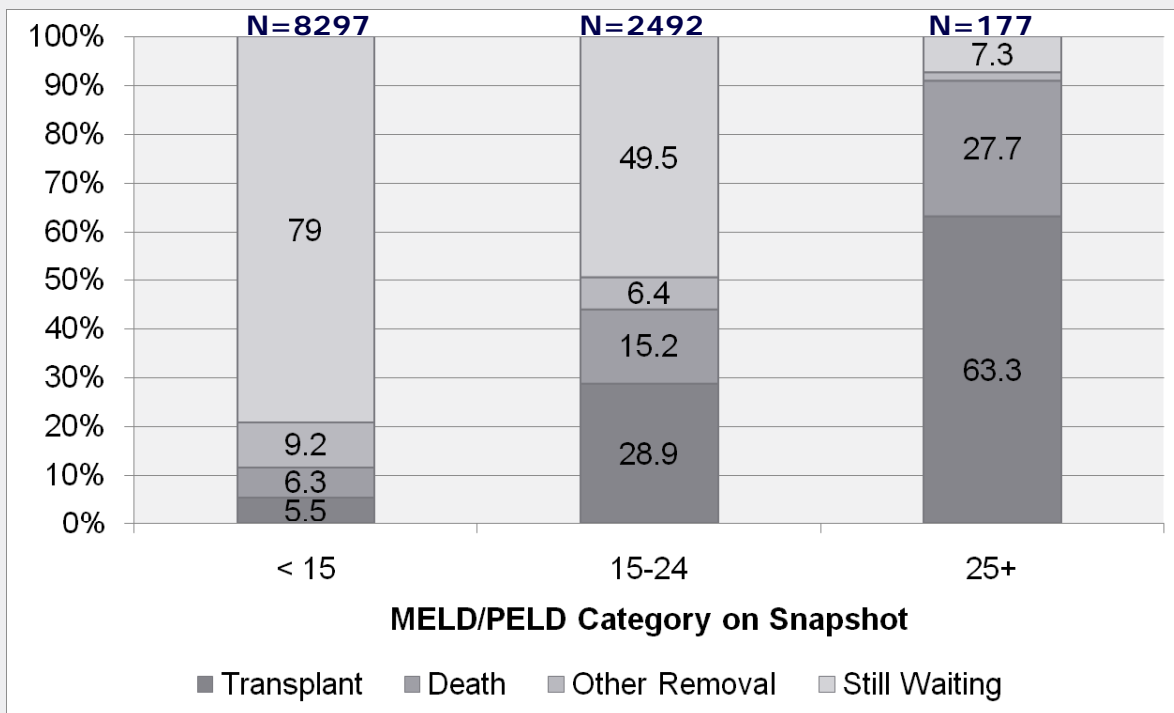
\* Includes removals for too sick



\*DSAs with less than 10 events not included



**Figure 6**  
**Competing Risk Liver Waiting List Outcome**  
**Probabilities at 1-Year**  
**Jan 2009 Snapshot\***



\*Excluding inactive and Status 1A/1B candidates, and exceptions

**Figure 7**  
**Median Distance vs.**  
**Decrease in Total Deaths**

