

# Liver and Intestinal Organ Transplantation Committee

Item for Board Consideration

November 11, 2013  
Atlanta, GA

# Proposal to Add Serum Sodium to the MELD Score

# Background

- MELD score implemented  
2/27/2002
  - Well-accepted & well-understood
  - Achieved goal of reducing waiting list mortality
  - Equation not modified since

# Background

- Sodium an important predictor of waiting list mortality
  - 11/2004 – OPTN began collecting sodium on waiting list
  - 2011-2012 – SRTR explored revisions/updates to MELD, including adding sodium and adjusting coefficient weights

Kim, WR, Biggins SW, Kremers WK, Wiesner RH, Kamath PSI, Benson JT, Edwards EB, Therneau TM. Hyponatremia and Mortality among Patients on the Liver-Transplant Waiting List. N Engl J Med 2008; 359:1018-1026

# Goal of the Proposal

- Reduce waiting list mortality rates by better prioritizing need
  - Without adversely impacting any specific group (by diagnosis, age, gender, ethnicity)
  - Greatest impact for those with low calculated MELD scores and low sodium (hyponatremia)

# How the Proposal will Achieve its Goal

- LSAM modeling data predicted 66 fewer waiting list deaths/year
- Committee reviewed alternatives (refitting MELD, with and without sodium)
  - Models ranged from 27-66 fewer WL deaths
  - For all options, total # deaths reduced ranged from 26 – 61

# Additional Background

- Still called MELD, still capped at 40
- Upper and lower bounds for sodium (125 to 137 mEq/dl)
  - Values < 125 mEq/dl receive same extra points as those with 125
  - Would not increase priority for candidates with risk of CPM
- Reduce number of requests for MELD exceptions for low sodium/ascites

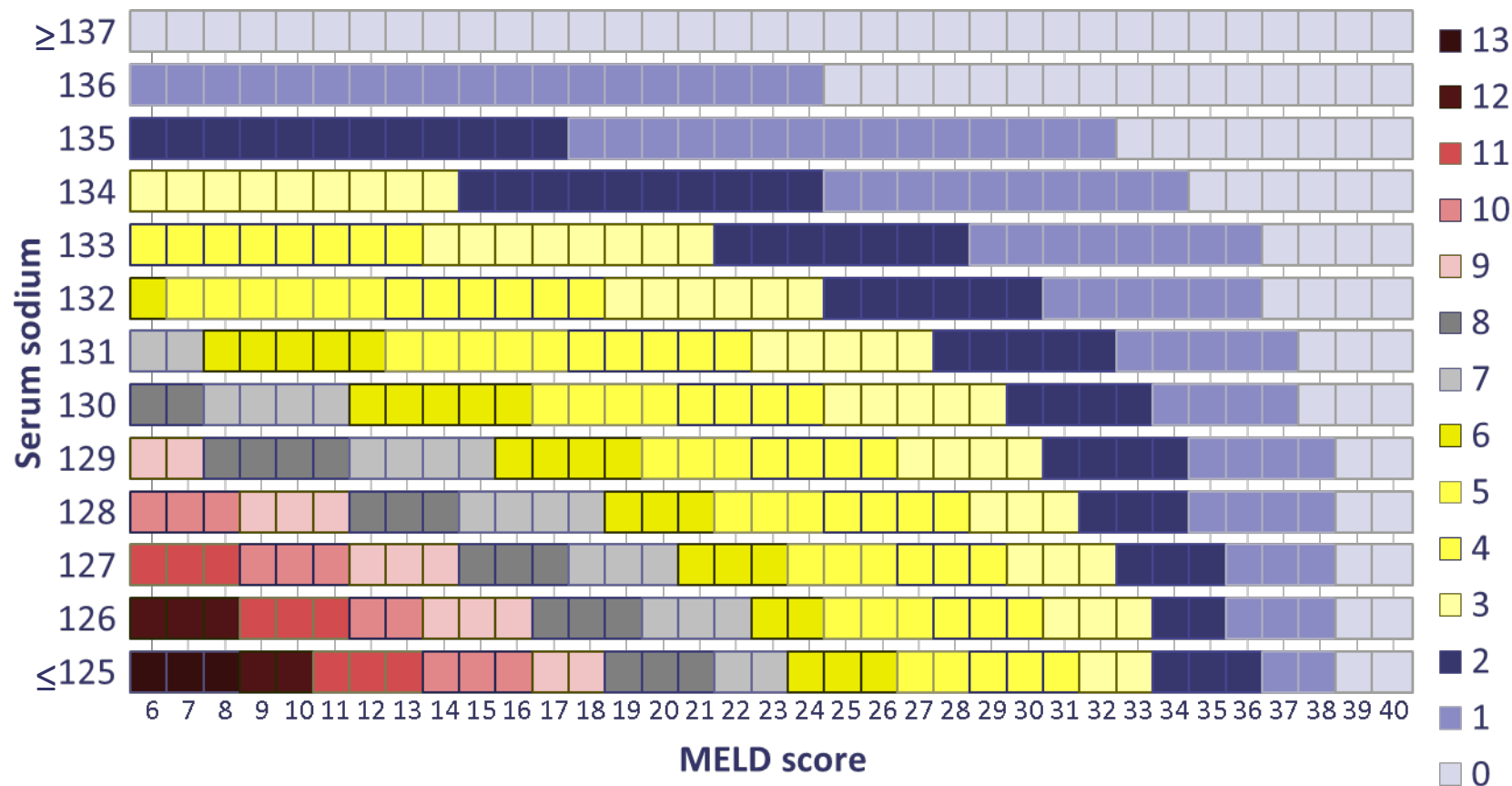
# Supporting Evidence

- Effect of low sodium and impact on MELD well-supported in literature
- C-statistic for MELD-Na = 0.877 (range 0.868 to 0.880)
  - Confidence levels of all c-statistics overlapped
  - All models similar to observed mortality for lower MELD values, higher than observed for higher MELD scores
- Modeling showed no adverse impacts by demographic/diagnostic group



# Impact of Sodium on the MELD Score

Additional MELD Points:



# Example: Revised MELD Score (with Sodium)

Creatinine = 1.9 mg/dL, bilirubin = 4.2 mg/dL, INR = 1.2,  
sodium = 133mEq/dl

1. Calculate original MELD<sub>(i)</sub> =  $(0.957 \times \text{Log}_e 1.9) + (0.378 \times \text{Log}_e 4.2) + (1.120 \times \text{Log}_e 1.2) + 0.643 = 2.0039$ , multiply by 10 and round: **20**
2. Formula: (Revised) MELD = MELD + 1.32 x (137-Na) – [0.033 x MELD\*(137-Na)]

Recalculate: MELD = **20** + 1.32\*(137-133) – [0.033\***20**\*(137-133)] = **23**

For Na = **127**, the new score would be **27**

For Na = **135**, the new score would be **21**

# Example: Revised MELD Score (with Sodium)

If the **MELD** is **15** and the **Na = 125**, the new score would be **25**

If the **MELD** is **15** and the **Na = 135**, the new score would be **17**

If the **MELD** is **30** and the **Na = 125**, the new score would be **34**

If the **MELD** is **25** and the **Na = 137**, the new score would be **25**

# Impact on Members

- Sodium already collected at all required intervals – no change
- Does not require changes to MELD parameters or mortality estimates:
- Programming required

# Public Comment Response

- Public Comments (32 responses), 28 with an opinion
  - 22 (78.6%) supported
  - 6 (21.4%) opposed
- Committees:
  - Minority Affairs: 18 Support, 0 Opposed
  - Patient Affairs: 17 Support, 0 Opposed 0
  - Transplant Administrators: 14 Support, 0 Oppose
  - Transplant Coordinators: 14 Support, 0 Oppose
- ASTS supported, AST opposed

# Regional Votes

Region	Motion to Approve as Written	Approved as Amended
1	12 yes, 0 no (2)	
2	29 yes, 0 no (0)	
3	8 yes, 4 no (0)	
4	10 yes, 11 no (5)	
5	26 yes, 3 no (4)	
6	0 yes, 41 no (0)	
7	18 yes, 1 no (0)	
8	17 yes, 2 no (0)	
9	16 yes, 0 no (1)	
10	15 yes, 7 no (4)	
11		23 yes, 0 no (2)

# MELD Sodium

## Specific Comments

- Correction for hyperglycemia
- May promote poor medical mgmt
- Can be “gamed”
- Should be done by RRBs

# Committee Response

- Voted to Eliminate the Requirement to Correct Sodium for High Glucose
  - Rare occurrence / minimum impact
  - Would require new data field in waiting list
  - Some Committee members still felt this should be considered
- Gaming / Poor Medical Management –
  - Could happen with current MELD, no evidence
- RRBs
  - Need national, consistent approach



# RESOLUTION 9, Page 30

- **RESOLVED**, that Policy 3.6.4.1 (Adult Candidate Status) shall be amended as set forth below, effective programming in UNet<sup>SM</sup> and notice to the OPTN membership.

$$\text{MELD Score}_{(i)} = (0.957 \times \text{Log}_e 1.9) + (0.378 \times \text{Log}_e 4.2) + (1.120 \times \text{Log}_e 1.2) + 0.643 = 2.0039$$

The MELD<sub>(i)</sub> score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical candidate in the example described above, therefore, would ~~be assigned a risk~~ have a MELD<sub>(i)</sub> score of 20. ~~The MELD score will be limited to a total of 40 points maximum.~~

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

The MELD score is then re-calculated as follows:

$$\text{MELD} = \text{MELD}_{(i)} + 1.32 \times (137 - \text{Na}) - [0.033 \times \text{MELD}_{(i)} \times (137 - \text{Na})]$$

This same candidate with a serum sodium level of 127 would have a MELD score of:

$$\text{MELD} = 20 + 1.32 \times (137 - 127) - [0.033 \times 20 \times (137 - 127)] = 27.$$

The MELD score will be limited to a total of 40 points maximum.

# QUESTIONS?

# **Liver and Intestinal Organ Transplantation Committee**

**Committee Update**

**November 11-12, 2013  
Atlanta, GA**

# Recent Policy Implementations

- Share 15/share 35/national share for combined liver-intestine candidates – implemented June 17, 2013
  - Committee will monitor impact of these changes
- HCC imaging criteria: October 31, 2013
  - Webinar on October 2, 2013
  - IT training sessions on 10/30 and 10/31, 2013

# Ongoing Committee Initiatives

- Review of Share 15/35/LI-IN and HCC Imaging
- HCC allocation proposals
  - 6-month delay
  - Exclude small, well-treated lesions from automatic points
  - Cap HCC score at 34
- Review of MELD/PELD exceptions and RRB practices
  - Working on guidelines for new standardized exceptions
- Revisiting the PELD allocation score

# Ongoing Committee Initiatives

OPTN

# Designing Liver Distribution for Geographic Equity



# Designing Liver Distribution for Geographic Equity - Recent Activity (Cont'd)

- November 2012: Board tasks Committees w/ Disparity Metrics
  - Liver Committee Metric: Variance of median MELD at transplant across DSAs
- March 2013: Liver Committee Key Decisions
  - Number of districts between 4 and 8
  - Minimum number of transplant centers per district: 6
  - Overall waitlist deaths must not be statistically significantly higher

# Designing Liver Distribution for Geographic Equity – Committee Progress Report

- September 2013: Reviewed drafts of maps
- Next steps:
  - Continued evaluation of impact of redistricting and comparison between 4 and 8 districts
    - Impact on pediatric patients
    - Impact on minorities
    - Waiting list deaths by DSA/District
    - Shift in livers by DSA/District
- Next Analyses: Upcoming Call

# Potential Path Forward

- Concept 'floated' Spring/Summer 2014
- Town Hall Meeting or Forum?
- Public Comment – Fall 2014?

# Designing Liver Distribution for Geographic Equity

## Broader Issues for Discussion

- POC decisions on overarching issues
  - Administrative Regions/RRBs
  - Contiguous/non-contiguous
  - Multiorgan issues
  - Role of DSA?
  - Organs other than livers – metrics?
- Impacts of OPO performance

# Questions on the Geography Project?

# Questions?