

Liver and Intestinal Organ Transplantation Committee
Conference Call
February 24, 2011 12:00 noon EST
Interim Report

1. Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization. The Committee reviewed this proposal put forward by the OPO and Membership and Professional Standards Committees. The MPSC is recommending that the OPTN implement a statistical model to evaluate OPO performance to identify opportunities for improving organ yield using a comparison of observed to expected organs transplanted per donor. Two models are proposed: an overall organs transplanted model and organ-specific yield models. There is no organ-specific yield model for intestines due to the small numbers involved. The c-statistic for the overall model was 0.83, and ranged from 0.78 to 0.90 for the organ-specific models; a c-statistic greater than 0.7 is generally considered clinically useful. Model outputs include:

- Number of donors
- Observed number of organs transplanted
- Expected number of organs transplanted
- Observed/Expected
- Two sided p-value
- Observed Yield per 100 Donors
- Expected Yield per 100 Donors
- Expected – Observed per 100 Donors

For two metrics, the absolute ratio of observed to expected and the difference in organs transplanted per 100 donors, the sponsoring Committees have selected a 10% difference as being a clinically relevant threshold for flagging (i.e., a ratio of observed to expected of less than 0.90). By applying these criteria to donors from 2008-2009, the models would have flagged seven OPOs out of the current 58: four with the overall model, and an additional three with the organ-specific model. This effort is intended as a trigger to begin a dialog with the OPO, rather than being a punitive action. Once an OPO is flagged, the MPSC will send a survey of inquiry and may follow-up with additional questions during the review. If an OPO does not demonstrate a plan for performance improvement or does not respond to the MPSC's requests, the MPSC may consider taking some adverse action. The OPO community is in support of this, as it is a better predictive model than the SCD/ECD/DCD model that is currently used, which was developed for kidneys and has been applied to other organs.

A Committee member asked why livers are only counted as one organ; the sponsoring committees did not consider split livers in their analyses of organs transplanted per donor. After discussion, the Committee indicated its support of the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

2. Concept Paper / Survey Results. The Committee reviewed the results of the Concept Paper survey that was open from December 31, 2010 through February 18, 2011. There were 227 responses, with 70% identified as being affiliated with a liver transplant program, and the remainder as either OPO personnel, or recipients/candidates/family/donors. Responses were received from every region and 36 states. A tabulation of the responses is shown in Table 1.

Table 1 Concept Paper Survey Results

Question	Yes	No
1. Would you support a national share 15 policy?	170 (74.9%)	57 (25.1%)
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?	107 (47.1%)	120 (52.9%)
3. Do you think broader sharing for patients with high waiting list mortality is reasonable?	178 (78.4)	49 (21.6)
4. Would you support regional sharing for a MELD/PELD threshold of (check all that apply):		
• 35	74 (32.6%)	
• 32	57 (25.1%)	
• 29	68 (30.0%)	
• None of the above	47 (20.7%)	
• Other	24 (10.6%)	
➤ Selected 29, 32, or 35, above	143 (63.0%)	
5. Should the Sharing Threshold (ST) concept be incorporated if tiered MELD/PELD sharing is endorsed?	185 (80.5%)	42 (18.5%)
6. Would you support a national policy for facilitated placement of donor livers that are not used locally or regionally?	208 (91.6%)	19 (8.4%)

Because respondents could select multiple thresholds for question 4, the percentages sum to greater than 100%. Some of the responses were difficult to interpret; for example, 26 answered that they would support a threshold of 32 only, making it unclear whether those would also support a higher threshold of 35 if it was proposed. Further, some individuals selected “none of the above” but in the text response indicated that a lower threshold or full regional sharing for all MELD/PELD scores should be considered. The combinations of responses are provided in Table 2. A total of 164 respondents (72%) selected some form of regional sharing (35, 32, 29, or other). The Committee also reviewed results by Region.

Table 2: Responses to Question 4: Would you support regional sharing for a MELD/PELD threshold of:

Share 35	Share 32	Share 29	Other share	None of the above	N	%
					16	7.1
				√	47	20.7
			√		21	9.3
		√			43	18.9
	√				26	11.5
√					41	18.1
√			√		2	0.9
√	√				6	2.6
√	√	√			24	10.6
√	√	√	√		1	0.4
Total					227	

27.8%

72.2%

A potential path forward for this initiative could be submission for public comment in the fall of 2011, with June 2012 being the earliest date of submission to the Board.

3. Liver Utilization Working Group. A review of the text responses to the Concept Paper survey regarding expedited placement highlighted several common themes. First, broader distribution at the offset would decrease the need for, “expedited placement” and would reduce the number of discards. Second, DonorNet could be modified to increase the number of initial offers than can be made at one time. And, third, pre-procurement biopsies would decrease discards. The Working Group has reviewed data for expedited placement (using national shares as a surrogate for expedited placement), as well as analyses of discarded livers. The group has asked for an analysis of factors common to national shares, offers that indicate ‘expedited placement’ or are made out of sequence, as well as discarded livers, to determine if there is a set of characteristics that could be used to define organs that could be considered for facilitated/expedited placement. The group has drafted a list of factors to be considered in the analysis.

The data show that approximately 50% of donors that are discarded have a discard reason of ‘biopsy findings.’ This has been seen as a subjective assessment. The OAC is working on a standardized biopsy form that will be presented to the Committee in March. It was reported that New York State has a pilot project using on-line biopsies; more information about this will be provided to the Committee.

The Committee discussed increasing the number of centers that receive initial offers, and/or decreasing the time for acceptance. Some members expressed concerns that centers will still indicate a ‘provisional yes’ but ultimately turn down the offer, leading to discard. The Effective Screening Working Group has been studying acceptance criteria for kidney offers, and is starting to look at livers. This group recently sent letters to kidney programs that routinely turn down offers that meet their acceptance criteria, in hopes the center would tighten up their criteria. There may be additional screening criteria that would be more useful to centers, such as how long after the liver has been procured.

**Committee Participation
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W. Kenneth Washburn, MD	Chair	X
Kim Olthoff, MD	Vice Chair	X
Michael Curry, MD	Regional Rep. Region 1	X
Stephen Dunn, MD	Regional Rep. Region 2	X
Brendan McGuire, MD	Regional Rep. Region 3	X
Goran Klintmalm, MD, PhD	Regional Rep. Region 4	
Ryutaro Hirose, MD	Regional Rep. Region 5	
Jorge D. Reyes, MD	Regional Rep. Region 6	X
Anthony D'Alessandro, MD	Regional Rep. Region 7	
Harvey Solomon, MD	Regional Rep. Region 8	X
Lewis Teperman, MD	Regional Rep. Region 9	X
John Fung, MD, PhD	Regional Rep. Region 10	
Michael Marvin, MD	Regional Rep. Region 11	
Scott Biggins, MD	At Large	X
Julie Heimbach, MD	At Large	X
Heung Bae Kim, MD	At Large	X
Timothy McCashland, MD	At Large	
Kenyon Murphy, JD	At Large	X
John Roberts, MD	At Large	
Debra Sudan, MD	At Large	
Kim Brown, MD	At Large	
Kareen Abu-Elmagd, MD	At Large	X
Michael Charlton, MD	At Large	
James Trotter, MD	At Large	
Thomas Mone	At Large	X
James Eason, MD	At Large	
Monica Lin, PhD	Ex Officio, HRSA	X
James Bowman, MD	Ex Officio, HRSA	X
Ba Lin, PhD	MMRF, SRTR Representative	X
Peter Stock, MD	MMRF, SRTR Representative	X
Yi Peng, MS	MMRF, SRTR Representative	X
Adrine Chung	MMRF, SRTR Representative	X
W. Ray Kim, MD	MMRF, SRTR Representative	X
Erick Edwards, PhD	UNOS, Assistant Director of Research	X
Ann Harper	UNOS, Policy Analyst	X
Brian Shepard	UNOS, Director of Policy	X
Jory Parker	UNOS, Business Analyst	X