

OPTN/UNOS Pediatric Transplantation Committee
Interim Report: July 20, 2011 Meeting
Teleconference/Live Meeting

David N. Campbell, M.D., Chair
Heung Bae Kim, M.D., Vice Chair

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its July 20, 2011, meeting.

The Pediatric Transplantation Committee (the Committee) met via teleconference to address two matters:

- The OPO Committee had requested that the Committee review potential policy language modifications to policy 7.1 (Reporting Definitions), specifically the imminent and eligible death definitions.
- Public comment feedback that was provided on the two proposals the Committee had out for consideration during the spring 2011 public comment cycle: Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B, and the Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B.

Joining the Committee on the call to help address any questions about the imminent and eligible death definitions were Jeff Orłowski, MS, CPTC, CEO of Center for Donation & Transplant (NYAP), and Rich Pietroski, MS, CPTC, Executive Director of Gift of Life Michigan (MIOP), Vice-Chair of the OPO Committee. To frame the discussion, call participants were reminded that these definitions are for reporting purposes only. The OPO Committee is modifying these definitions within the policy to achieve more consistent reporting by OPOs.

To initiate the discussion, the Committee liaison read feedback that had been provided by the Vice-Chair of the Committee, who was unable to join the call. The first comment was, "I would decrease the minimum weight to 3kg." Other Committee members on the call were curious how the 5kg lower weight limit was established. Mr. Orłowski stated that the OPO Committee had reviewed UNOS data describing imminent and eligible donors, and there were very few examples (no more than 10 was the approximation given) of donors that weighed less than 5kg. After considering a few lower weight thresholds, the OPO Committee elected to use 5kg to reduce the data burden that would result from the number of cases that would fall below the 5kg lower threshold, but that rarely yield a donor (as indicated by the data reviewed by the OPO Committee). He continued that over 99.6% of recovered donors are captured by the requirements as they are currently drafted: weight 5kg or greater, BMI of 50 kg/m² or less, and 70 years old or younger. He then reminded the Committee that these definitions are not rule-out criteria; rather, they are for reporting purposes only. An OPO will still get credit for recovering a donor that is outside of these criteria, but is not penalized if that is not achieved.

A Committee member question if there was any numerical support regarding the data burden that would be avoided by using 5kg versus 3kg. Mr. Orłowski responded that the Committee is unaware of how many under 5kg are referred. The Committee member responded that it is hard to justify the 5kg lower threshold citing data burden when the potential impact is not really well understood. Assuming that the number of donors is approximately evenly distributed across all OPOs, he opined that the number of donors in this weight range would not cause a significant data burden increase, but would be worth pursuing because of the extra challenge that pediatric transplant candidates face trying to find size appropriate donors. He was concerned that OPO's not being held accountable for donors of this size

could result in an unintended consequence of OPO's not pursuing these donors. Mr. Orłowski replied that this unintended consequence is not likely in reality, partly because the OPO would receive credit for organs donated, even if the donor is outside these criteria. Mr. Orłowski again reminded the group that these definitions were not rule-out criteria, but an effort to capture the most reported deaths that result in donated organs while minimizing the effort exerted on those cases that often do not result in donors being realized. The Committee member replied he was thankful that the OPO Committee was considering the data burden of these modifications, relative to their usefulness.

The Committee liaison read another comment provided before the call that said, "Consider adding a minimum post-gestational age which I would set at 38 weeks, i.e. if a child was born at 38 weeks gestation (term is 40) or later, they would always be eligible, but if they were at 36 weeks gestation and were only 1 week old, they would not be eligible. This may be too complicated, but it does make practical sense as it will rule out premature infants even if they meet size criteria." Committee members did not believe that premature infants would meet the 5kg threshold, and thus the added complexity is not worth pursuing.

Another Committee member wanted to confirm her understanding that donors after circulatory determination of death (DCDD) were not included in the definitions. Mr. Orłowski confirmed that was correct. In response to this, the Committee member stated that DCDD is becoming more and more common, and future revisions of these definitions should consider incorporating it as a part of the imminent and eligible death definitions.

Another Committee member questioned if the final bullet in the modified Policy 7.1.6 (Eligible Death Definitions) was redundant with respect to all those items listed in the preceding bullets. Mr. Orłowski indicated that this does seem to be the case, and would refer this point back to the OPO Committee.

An OPO representative of the Committee stated that the proposed changes are a drastic improvement on the current definitions. He asked if different upper age limits were considered depending on the organ, alluding to the unlikely scenario of thoracic organs being placed from a donor that is much older than 60 years of age. Mr. Orłowski stated that this had been discussed, but the OPO Committee felt that having a consistent age range (0-70 years) for all organs would yield more consistent reporting. The concern was that varying age ranges would add complexity that would result in more confusion and inaccurate reporting. The Committee member also asked why an elevated creatinine was not included as a kidney specific criterion. The Committee's crossover representative to the Kidney Committee replied that she had asked the same question, and was informed that there are some donors who reach an extremely high creatinine, but that value begins to decline, and these kidneys are successfully transplanted. Mr. Orłowski concurred that this was the rational, based on previous guidance the OPO Committee had received from the kidney transplant community.

This discussion ended with thanks from Mr. Orłowski for the Committee's time and feedback. He stated the Committee provided helpful remarks that will strengthen the formal public comment proposal that is being developed.

Call participants proceeded to discuss the feedback that had been provided for those two proposals the Committee had out for consideration during the spring 2011 public comment cycle. The Committee first reviewed the feedback for the proposal that recommends all candidates with hepatoblastoma be listed as Status 1B. Exhibit 1 summarizes the feedback that was provided, and includes the Committee's responses to that feedback. Following this discussion, the Committee reviewed those comments provided for the proposal that recommends that the ICU requirement for pediatric Status 1A/1B liver candidates be eliminated. Exhibit 2 summarizes the feedback that was provided for this proposal, and also includes the Committee's responses to that feedback.

Next the committee reviewed the proposed policy language. Considering the support for both proposals, the committee agreed that it is unnecessary to state that hepatoblastoma candidates do not need to be admitted to the ICU. Assuming both proposals are adopted, this information would be unnecessary. If the hepatoblastoma proposal is supported by the Board of Directors, but not the removal of the ICU requirement, this clarifying sentence would remain. The Committee liaison informed the committee that these responses discussed would be documented, and then this information and the final policy language will be shared with the entire Committee. At this point, the Committee will be asked to vote on if they support submitting these two proposals for the Board of Director's consideration at its November 2011 meeting.

To conclude the call, the Committee was reminded of its past discussion regarding *in utero* heart listings. There was a general sentiment that these listings are not necessary, and these policies should be deleted. Before acting on this, the Committee wanted to gauge the community's support for these changes. If there are no major concerns raised, then the Committee will propose deleting these policies. This call concluded with a reminder for the Committee that this discussion will be had in September, and they should reach out to their colleagues in preparation for it.

OPTN/UNOS Pediatric Transplantation Meeting
 July 20, 2011 Meeting
 Teleconference/Live Meeting

NAME	COMMITTEE POSITION	On the Phone
David Campbell, MD	Chair	X
Heung Bae Kim, MD	Vice Chair	
Laura O'Melia, CPNP	Regional Representative	
Stephen Dunn, MD	Regional Representative	X
Alfonso Campos, MD	Regional Representative	
Jose Almeda, MD	Regional Representative	X
Debra Strichartz, RN, BA, CCTC	Regional Representative	
Andre Dick, MD, FACS	Regional Representative	X
Sharon Bartosh, MD	Regional Representative	X
Jeffrey Lowell, MD	Regional Representative	
Kishore Iyer, MD	Regional Representative	X
Jeff Shuhaiber, MD	Regional Representative	
Kathy Jabs, MD	Regional Representative	X
Sandra Amaral, MD	At Large	
Eileen Brewer, MD	At Large	X
John Bucuvalas, MD	At Large	X
Blanche Chavers, MD	At Large	
Shylah Haldeman, RN	At Large	
Clifford Chin, MD	At Large	X
Carmen Cosio, MD	At Large	X
Alan Farney, MD, PhD	At Large	
Simon Horslen, MB, ChB	At Large	
Kimberly Hoagwood, PhD	At Large	
William Mahle, MD	At Large	X
Debbi McRann, RN	At Large	X
Douglas Milbrath	At Large	X
Gary Visner, DO	At Large	
Jerry Wright, RN, CPTC	At Large	X
James Bowman, MD	HRSA	X
Monica Lin, PhD	HRSA	
Ba Lin, MS, MPH	HRSA	X
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Cheryl Hall	UNOS Business Analyst	X
Franki Chabalewski, RN, MS	OPO Committee Liaison	X
Jeff Orlowski, MS, CPTC	behalf of OPO Committee	X

NAME	COMMITTEE POSITION	On the Phone
Rich Pietroski, MS, CPTC	behalf of OPO Committee	X
Sam Davis	past Committee member	X
Scott Elisofon, MD	past Committee member	X
Manuel Rodriguez-Davalos, MD	past Committee member	X

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B

1. Public Comment Distribution

Date of distribution: 03/11/2011

Public comment end date: 06/10/2011

Public Comment Response Tally					
Type	Response Total	In Favor	In Favor as Amended	Opposed	No Comment
Individual Comments	14	9 (100%)	NA	0	5
Regional Comments	11	11 (100%)	NA	0	0
Committee Comments	21	2 (66.6%)	NA	1 (33.3%)	18

2. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	3/28/2011	12 yes, 0 no, 1 abstentions		
2	4/1/2011	18 yes, 0 no, 2 abstentions		
3	4/1/2011	13 yes, 0 no, 2 abstention		
4	5/20/2011	22 yes, 1 no, 0 abstention		
5	6/9/2011	31 yes, 0 no, 0 abstentions		
6	5/20/2011	34 yes, 0 no, 0 abstentions		
7	5/20/2011	13 yes, 0 no, 0 abstentions		
8	4/8/2011	17 yes, 0 no, 0 abstentions		
9	3/16/2011	20 yes, 0 no, 1 abstention		
10	4/8/2011	18 yes, 0 no, 1 abstention		
11	6/10/2011	16 yes, 0 no, 0 abstentions		

Region 1: One member commented that if this policy is approved the SRTR should modify the risk ratio for pediatric liver candidates.

Committee Response:

The sponsoring committee appreciates this support. Regarding the risk ratio for pediatric liver candidates, the Committee was unsure how the SRTR calculates risk ratio for pediatric liver candidates with respect to hepatoblastoma. The data indicates that these changes will primarily impact these candidates time to transplant, with negligible impact to other demographics of liver candidates. The Committee was not aware of any data that shows a correlation between outcomes and time hepatoblastoma candidates are on the waiting list. These changes are being proposed to improve these candidates access to liver offers at the appropriate time, allowing for optimal treatment and management of their condition. Additionally, because of the relatively small number of pediatric liver candidates that are listed with hepatoblastoma, changes within this small subset of patients is not likely to have a significant impact on the risk ratio that is applied to all pediatric liver candidates.

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B

3. Committee Public Comment Responses

Liver and Intestinal Organ Transplantation Committee

The Committee has already endorsed this proposal and continues to do so.

Committee Response:

The sponsoring committee appreciates this support.

Patient Affairs Committee

The Committee heard the proposal and voted without comment. (VOTE: Support – 1, Oppose – 10, Abstain- 3)

Committee Response:

*It is difficult to address the Patient Affairs Committee's (PAC) concerns without additional feedback summarizing their opposition. Based on the summary (drafted by a PAC member, provided by the PAC liaison) that the PAC used to review the proposal prior to their meeting, the Committee understands most of the concerns stemmed from a feeling that other Status 1B patients will be disadvantaged by this change. This feeling was supported by the notion that waiting time is what prioritizes multiple Status 1B candidates in the same classification, and "this proposal basically gives hepatoblastoma patients an extra 30 days of waiting time." This proposed policy change **does not** give a candidate extra waiting time so that they may be listed as Status 1B. Rather, the proposal recommends eliminating the requirement that a candidate with hepatoblastoma must be listed at a MELD/PELD score of 30 for 30 days before being listed as a Status 1B. If adopted, the Committee's intent would be for a candidate with a biopsy-confirmed hepatoblastoma to have the option of being listed as Status 1B, at which point their accumulation of waiting time would be initiated.*

Referencing the Children's Oncology Group (COG) protocol, the summary also indicated that because there is a waiting period of a few weeks between cycles of chemotherapy, there needs to be some delay. A Committee member who is a part of the surgical committee for this COG study indicated that after the fourth cycle of chemotherapy additional complications (e.g. permanent sensory neural hearing loss, post-transplant renal insufficiency) become more prevalent. Transplanting hepatoblastoma candidates in the small, optimal window of opportunity has the potential to mitigate these complications. Along these lines, a primary goal of the COG's recommendations for candidates with hepatoblastoma is to get them into the transplant system as soon as possible, rather than near the end of their chemotherapy treatment. These proposed changes would support that goal.

A final point the Committee discussed suggested that the impact of these changes on other Status 1B candidates should be evaluated. The Committee recognizes and appreciates this point, and if adopted, it intends to analyze the waiting list mortality and transplant rate of all Status 1B candidates (excluding those with hepatoblastoma), as indicated in the proposal.

Transplant Administrators Committee

The Committee discussed and unanimously supported this proposal as written. (11-Support, 0-Oppose, 0-Abstain)

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B

Committee Response:

The sponsoring committee appreciates this support.

4. Individual Public Comment Responses

Comment 1:

vote: Support

Date Posted: 06/14/2011

NATCO appreciates the opportunity to provide input/comments on the following policy.

Committee Response:

The sponsoring committee appreciates this support.

Comment 2:

vote: Support

Date Posted: 06/13/2011

ASTS supports this proposal that will provide additional priority for pediatric patients with hepatoblastoma. However, ASTS suggests that monitoring of post-transplant outcomes be added to the proposal.

Committee Response:

The sponsoring committee appreciates this support. The Committee agrees that monitoring post-transplant outcomes of these patients would be useful in assessing the impact of these changes.

Comment 3:

vote: Support

Date Posted: 06/10/2011

See the attached letter.

Committee Response:

The sponsoring committee appreciates this feedback.

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B



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To: OPTN/UNOS Pediatric and Liver & Intestinal Organ
Transplantation Committees

From: American Society of Transplantation

Re: Proposal to List All Non-Metastatic Hepatoblastoma
Pediatric Liver Candidates as Status 1B

Date: June 9, 2011

Thank you for inviting comments from the American Society of Transplantation (AST) on the proposal to list all non-metastatic hepatoblastoma pediatric liver candidates as Status 1B. Members of the AST Pediatric and Liver & Intestinal Communities of Practice were solicited for their feedback regarding the proposal. The comments listed below have been approved by the AST Executive Committee.

Comments

There is overarching support for this proposal. The proposal as written will reduce waiting time for patients with hepatoblastoma and does not appear to disadvantage other liver recipients in any way. The AST Pediatric Community of Practice did not feel there was anything contentious or detrimental to pediatric patients in the proposal.

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AMERICAN TRANSPLANT
CONGRESS 2012

June 2-6, 2012
Boston, MA

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B

1. Public Comment Distribution

Date of distribution: 03/11/2011

Public comment end date: 06/10/2011

Public Comment Response Tally					
Type	Response Total	In Favor	In Favor as Amended	Opposed	No Comment
Individual Comments	14	7 (100%)	NA	0	7
Regional Comments	11	10 (91%)	NA	1 (9%)	0
Committee Comments	21	4 (100%)	NA	0	17

2. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	3/28/2011	12 yes, 0 no, 1 abstentions		
2	4/1/2011	18 yes, 0 no, 2 abstentions		
3	4/1/2011	12 yes, 1 no, 2 abstention		
4	5/20/2011	10 yes, 5 no, 8 abstention		
5	6/9/2011	27 yes, 0 no, 0 abstentions		
6	5/20/2011	34 yes, 0 no, 0 abstentions		
7	5/20/2011	3 yes, 9 no, 1 abstentions		
8	4/8/2011	16 yes, 0 no, 0 abstentions		
9	3/16/2011	20 yes, 0 no, 1 abstention		
10	4/8/2011	16 yes, 2 no, 1 abstention		
11	6/10/2011	16 yes, 0 no, 0 abstentions		

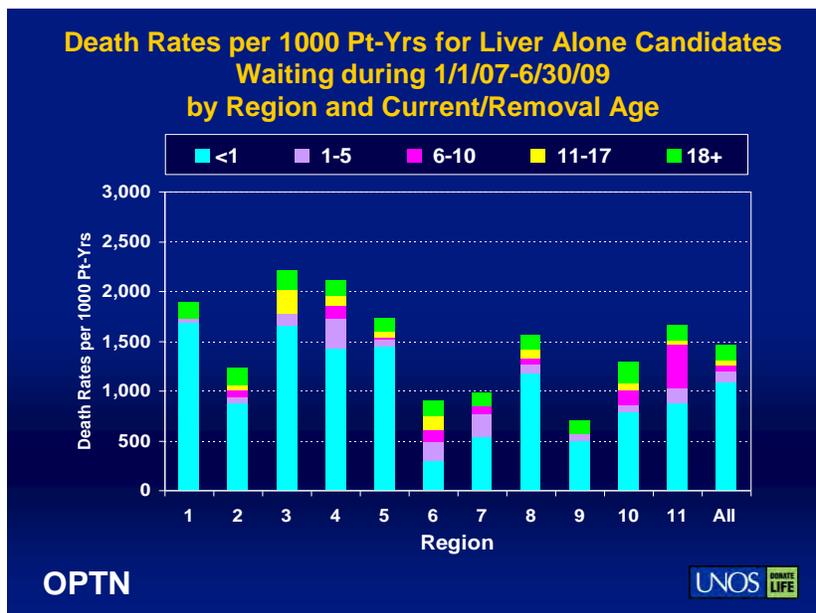
Region 4: Several members commented that this proposal will negatively impact adult candidates waiting for a liver transplant. Adult candidates have a higher mortality on the waiting list. Children listed as Status 1A and 1B is already on the rise in Region 4, and will continue to increase if this policy is approved.

Committee Response:

The sponsoring committee appreciates the vote of support.

The Committee recently analyzed death rates per 1000 patient years for liver alone candidates that were waiting between 1/1/07-6/30/09. With respect to death rates, these data indicate that adults do not have a higher mortality on the waiting list.

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital’s Intensive Care Unit to Qualify as Status 1A or 1B



The Committee does not believe that this proposal will negatively impact adult candidates waiting for a liver transplant. The Committee believes that the current requirements for a pediatric liver candidate to be listed as Status 1A or 1B are still stringently defined without the ICU requirement. Furthermore, it is not uncommon for pediatric liver candidates that meet the Status 1A/1B criteria outlined in policy except the ICU requirement to be listed as Status 1A or 1B. These situations are submitted as special cases, and routinely deemed reasonable by the Review Subcommittee of the Liver Committee. Considering these two points, the Committee does not anticipate a dramatic increase in the number of pediatric liver candidates that are listed as Status 1A or 1B.

Region 7: The region did not approve this proposal because they were very concerned that by removing this requirement there exists the potential for candidates to be listed at these statuses who are not even in the hospital. Several members of the audience were part of formulating the original policy language which was developed to counteract unfair listing practices and they are not convinced that the current policy provides enough safeguard to now remove this provision.

Committee Response:

The Committee appreciates your consideration of this proposal. The Committee contends that the current Status 1A/1B ICU requirement promotes less fair listing practices than if the ICU requirement was eliminated. Due to varying ICU admission criteria across the country, the ICU requirement yields inconsistent listings that could be seen as unfair.

The Committee also believes the current Status 1A/1B criteria are stringent enough without the ICU requirement. This proposal does not recommend any other changes to the otherwise objective pediatric Status 1A and 1B listing criteria. Although a few exceptions were noted, the Committee feels the current pediatric Status 1A and 1B criteria reflect a candidate who has been admitted to the hospital, and is most likely in the ICU. Additionally, it is not uncommon today for pediatric liver candidates that

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital’s Intensive Care Unit to Qualify as Status 1A or 1B

meet the Status 1A/1B criteria outlined in policy except the ICU requirement to be listed as Status 1A or 1B. These situations are submitted as special cases, and routinely deemed reasonable by the Review Subcommittee of the Liver Committee. The Committee encourages those that are concerned with this proposed modification to review those cases in the table below that reflect the 25 listings from 9/1/05–7/31/09 where a Status 1A/1B special case was approved and the sole reason the candidate did not meet the established criteria was because the candidate was not in the ICU. The Committee believes these are examples of high acuity cases, regardless if the candidate has been admitted to the ICU. For example, 9/10 Status 1A patients were either acute liver failure patients, Wilson disease or hepatic artery thrombosis (criteria for Status 1A listing) and 15/15 Status 1B patients, who were candidates for combined liver intestine, would meet Status 1B criteria (transfusion criteria, etc). Although these special cases are customarily approved, it is not known if every transplant center takes advantage of this listing practice. To have a “work around” solution that some centers successfully use, but others are unaware or hesitant of, also could be seen as unfair. Ultimately, the Committee believes the severity of a candidate’s illness should dictate their status, regardless of their physical location.

Pediatric Status 1A/1B exception cases during 9/1/05–7/31/09 where the sole reason that the candidate did not meet criteria was 'Candidate not in the ICU'

	Status				All	
	Status 1A		Status 1B			
	N	%	N	%	N	%
Diagnosis						
ACUTE LIVER FAILURE	1	10	0	0	1	4
ESOPHAGEAL ATRESIS, CIRRHOSIS OF LIVER	0	0	1	7	1	4
FULMINANT HEPATIC FAILURE	2	20	0	0	2	8
FULMINANT HEPATIC FAILURE NON A, NON B, NON C	1	10	0	0	1	4
HEPATIC ARTERY THROMBOSIS	3	30	0	0	3	12
IDOPATHIC	1	10	0	0	1	4
JEJUNAL ATRESIA; SHORT-GUT	0	0	1	7	1	4
NECROTIZING ENTEROCOLITIS	0	0	5	33	5	20
SHORT GUT SYNDROM AND TPN CHOLESTASIS	0	0	2	13	2	8
SHORT GUT SYNDROME	0	0	1	7	1	4
SHORT GUT SYNDROME, TPN CHOLESTASIS, GI BLEEDING	0	0	2	13	2	8
TPN CHOLESTASIS	0	0	3	20	3	12
WILSON'S DISEASE	2	20	0	0	2	8
All	10	100	15	100	25	100

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B

3. Committee Public Comment Responses

Liver and Intestinal Organ Transplantation Committee

The Committee has already endorsed this proposal and continues to do so.

Committee Response:

The sponsoring committee appreciates this support.

Patient Affairs Committee

The Committee heard the proposal and voted without comment. (Support – 15, Oppose –0, Abstain-0)

Committee Response:

The sponsoring committee appreciates this support.

Transplant Administrators Committee

The Committee discussed and unanimously supported this proposal as written. (11-Support, 0-Oppose, 0-Abstain)

Committee Response:

The sponsoring committee appreciates this support.

Transplant Coordinators Committee

The Committee voted in support of this proposal with no comments. (Support- 13, Oppose – 0, Abstain 0)

Committee Response:

The sponsoring committee appreciates this support.

4. Individual Public Comment Responses

Comment 1:

vote: Support

Date Posted: 04/02/2011

I feel secure enough that attending doctors will know when it is time for a transplant, and will not transplant before it is absolutely necessary. I also feel this will help eliminate any additional health care costs incurred by the patient and families.

Committee Response:

The sponsoring committee is in full agreement, and appreciates this feedback.

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B

Comment 2:

vote: Support

Date Posted: 06/14/2011

NATCO appreciates the opportunity to provide input/comments on the following policy.

Committee Response:

The sponsoring committee appreciates this support.

Comment 3:

vote: Support

Date Posted: 06/13/2011

ASTS supports this proposal that eliminates location as a surrogate for severity of illness.

Committee Response:

The sponsoring committee appreciates this support.