

**Report of the Meeting of the Thoracic Committee and Pediatric Committee**  
**June 19, 2012**  
**Teleconference and Live Meeting**  
**4:30 pm to 5:30 pm (Eastern)**

*Thoracic Committee Members:* Steve Webber, Joseph Cleveland, Kevin Dushay, David (Brad) Dyke, Ted Liou, Bill Mahle, Brigette Marciniak-Bednar, Ken McCurry, Damian Neuberger, TP Singh, Stuart Sweet, David Vega, Mark Zucker, Mark Barr

*Pediatric Committee Members:* Clifford Chin Sandra Amaral, Sharon Bartosh, Eileen Brewer, Sandy Amara, Clifford Chin, William Mahle

*SRTR Staff Members:* Brooke Heubner, Monica Colvin-Adams, Melissa Skeans, Jodi Smith, Susan Leppke

*HRSA Representatives:* Ba Lin, Monica Lin, Jim Bowman

*UNOS Staff Members:* Leah Edwards, Elizabeth Miller, Jory Parker, Liz Robbins, Chad Waller, Elizabeth Sleeman, Wida Cherikh, Vipra Ghimire

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The Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee (“the Committees”) met on June 19, 2012 to discuss the Pediatric/Heart Workgroup’s (“the Workgroup”) proposed changes to the pediatric heart policies. After fielding input from the community, the Workgroup decided to focus on modifications to four areas: 1) *in utero* listings; 2) Status 1A criteria to deemphasize wait time and re-focus on medical urgency; 3) ABO incompatibility policy; and 4) the allocation priority of infant heart candidates. The draft the Committees reviewed during the teleconference is copied at the end of this document.

*In Utero Policy Modifications*

The Committees felt comfortable eliminating *in utero* listings from the policy due to the small number of listings per year, but would like to determine what to do if there is a candidate listed *in utero* at the time the policy is implemented. One suggestion is to monitor whether there are any candidates listed *in utero* prior to the approval of the policy (currently there are no *in utero* listings).

*Pediatric Heart Status 1A Modifications*

The Committees first discussed changes to Status 1A(e), which would include requiring a “hemodynamically significant congenital heart disease” diagnosis and admission to the listing center, in addition to the already-existing requirement for infusion of high dose or multiple inotropes. When the policy was being drafted, there was concern that if congenital heart disease diagnoses were not specified, candidates may be listed that did not have hemodynamically significant heart disease. However, listing all qualifying congenital heart diseases, perhaps through a drop box option, would be too complicated because the list of qualifying diseases would be too long and might be incomplete. Though some suggested that auditors would be able to determine whether someone was abusing the policy and listing candidates with “trivial” congenital diseases, the Committees were informed that the site auditors are not

capable of identifying what is “trivial.” Ultimately the Committees agreed that including a list of examples of qualifying hemodynamically significant congenital heart diseases was the proper balance to strike because it shows general expectations.

The Status 1A by exception section must clearly state that Review Board approval is retrospective, and the Committees were also concerned that there was not enough guidance for how the Review Board should review exception cases. However, because the RRB policy is being revised currently in another project, this section is likely to be changed in the future, so the Committees refrained from making substantive changes at this time.

The Committees also recognized the need to make Status 1A and 1B requirements mutually exclusive, so the language needs to be clarified to explicitly distinguish 1B criteria from 1A criteria. The Committees also agreed that the specific inotropic drips shouldn't be listed in the description of Status 1B qualifying criteria because they were not listed in Status 1A. The Status 1B exception should be changed to match the language in the Status 1A exception.

### ABO Incompatibility Policy

The Committees agreed to modify the pediatric ABO incompatibility policy to keep pace with recent medical findings. The Committees expect that the change in isohemagglutinin titer threshold will allow transplant centers to list more pediatric candidates, and the change in blood group matching, to primary and secondary status, will increase the possibility that the pediatric candidates will receive heart offers.

Though current policy requires the Pediatric Committee to monitor the data that originates from the implementation of these pediatric policies, in practice there have been no such transplants for pediatric candidates between one and two years of age thus far. The only ABO-incompatible transplants that have been performed since the implementation of the policy in November 2010 were in candidates that are less than one.

For infants, there are no data suggesting that ABO compatibility is relevant to transplant outcome, so it should not be a factor for pediatric heart allocation. The more difficult issue is modifying “ABO incompatible” transplants for older pediatric candidates. The Committees considered removing the “primary” and “secondary” stratifications, but ultimately chose to retain them because, even though the data show ABO incompatible transplants can be successful in pediatric candidates, the data itself is too limited to make these distinctions into policy. Additionally, some physicians and surgeons may be hesitant to accept an ABO incompatible organ for a relatively stable candidate, and may prefer to continue stratifying blood type matching based on the primary and secondary stratifications, so the Committees decided retain the distinctions.

The current policy was conservative regarding the isohemagglutinin titer requirements because there were no data about the long term outcomes of controlled blood group-incompatible heart transplants when it was originally proposed in 2006. But, because data demonstrate that pediatric recipients can successfully receive a transplant from a blood type incompatible donor, at nearly the same success rates as infant candidates, the policy should be changed to reflect this reality.

The Committees chose a conservative approach to allow transplants for candidates, at least one year of age at the time of the match run, but less than two years of age at the time of listing, with a blood type

incompatible with the donor, to receive an incompatible blood type organ as long as the candidate's isohemagglutinin titer is 1:16 or less. The Committees based this policy on empirical evidence, but 1:16 is still a conservative number as transplants have been successfully performed for candidates with even higher isohemagglutinin titers. The Committees also considered not putting an exact isohemagglutinin titer into policy, to ensure that if future data reveals that an even higher isohemagglutinin titer still yields a successful transplant outcome, the policy can be flexible enough to accommodate such transplants, but the Committees ultimately decided to keep the maximum isohemagglutinin titer at 1:16 for clarity.

## **Proposed Pediatric Heart Policy Modification [Draft for June 19, 2012]**

~~**3.2.1.6 Registration of In Utero.** Transplant Candidates. Registration of an in utero transplant candidate on the Waiting List is appropriate only when prenatal diagnostic tests confirm that the in utero candidate is viable and medically suitable to receive an organ transplant. The risk of associated complications becomes appropriately low at between 32 and 36 weeks gestation. An in utero transplant candidate shall be listed under a special status code on the Waiting List.~~

~~**3.2.1.7 In Utero Waiting Time.** If an in utero candidate is not assigned a thoracic organ transplant prior to delivery on the basis of Policy 3.2.1.6, the candidate's waiting time will recommence from the time of birth with the candidate listed under the regular status code.~~

**3.7.4 Pediatric Candidate Status.** Each candidate added to the heart transplant Waiting List prior to his or her 18<sup>th</sup> birthday receives a status code corresponding to the candidate's medical urgency for transplant, according to the following criteria:

Status \_\_\_\_\_ Definition

Status 1A \_\_\_\_\_ A candidate classified as Status 1A meets at least one of the following criteria:

- (a) \_\_\_\_\_ Requires assistance with a ventilator
- (b) \_\_\_\_\_ Requires assistance with a mechanical circulatory support device
- (c) \_\_\_\_\_ Requires assistance with an intra-aortic balloon pump
- (d) \_\_\_\_\_ Has ductal dependent pulmonary or systemic circulation with ductal patency maintained by stent or prostaglandin infusion
- (e) \_\_\_\_\_ Has a congenital heart disease diagnosis (excluding minor lesions of no, or minimal, hemodynamic significance such as isolated atrial septal defect, small ventricular septal defect, PDA, or bicuspid aortic or pulmonary valve); is admitted to the listing center hospital; and, requires infusion of high dose or multiple inotropes.

The OPTN Contractor shall maintain a list of the specific inotropes and doses approved by the Board of Directors for compliance with this criterion.

Or (Option 2 for criterion e)

Has a congenital heart disease diagnosis; is admitted to the listing center hospital; and, requires infusion of high dose or multiple inotropes.

The OPTN Contractor shall maintain a list, in UNet<sup>SM</sup>, of the specific inotropes and doses approved by the Board of Directors for compliance with this criterion.

*Or (Option 3 for criterion e) – Lists the Inotropic support in policy*

Has a congenital heart disease diagnosis; is admitted to the listing center hospital; and, requires infusion of high dose or multiple inotropes. Below is a list of inotropic agents and support that meet this policy.

**Table 1: Acceptable Inotropic Agents and Support**

<b>Acceptable High-Dose Inotropes</b>	<b>Acceptable Multiple Inotropes</b>
<u>Epinephrine &gt; 0.02 mcg/kg/min</u>	<u>Dobutamine with epinephrine, dopamine, milrinone, or norepinephrine</u>
<u>Dobutamine &gt; 7.5 mcg/kg/min</u>	<u>Dopamine with epinephrine, dobutamine, milrinone, or norepinephrine</u>
<u>Dopamine &gt; 7.5 mcg/kg/min</u>	<u>Milrinone with epinephrine, dobutamine, dopamine, or norepinephrine</u>
<u>Milrinone &gt; 0.5 mcg/kg/min</u>	<u>Epinephrine dobutamine, dopamine, milrinone, or norepinephrine</u>

A candidate may be classified as Status 1A by criterion (a), (b), (c), (d), or (e) for 14 days. A candidate’s attending physician can renew the Status 1A classification for an indefinite number of 14-day periods, as long as the candidate continues to meet criterion (a), (b), (c), (d), or (e).

**Status 1A by Exception**

A physician may classify a candidate who does not meet criterion (a), (b), (c), (d), or (e) as Status 1A by criterion (f) if the candidate’s life expectancy without a heart transplant is less than 14 days. This classification will be evaluated by the Regional Review Board. A candidate’s attending physician can renew the classification of Status 1A by criterion (f) for a single 14-day period. Further extension of the Status 1A classification by criterion (f) requires the attending physician to communicate by phone with the applicable Regional Review Board. If the Regional Review Board denies the request, the attending physician may still classify the candidate as Status 1A. In this instance, the Thoracic Organ Transplantation Committee will review the Regional Review Board’s decision and accompanying rationale. The Thoracic Organ Transplantation Committee may refer any case it reviews to the Membership and Professional Standards Committee.

Status 1B A candidate classified as Status 1B meets at least one of the following criteria:

- (a) Requires infusion of one or more intravenous inotropic agents listed below **and does not meet the Status 1A(e) criterion**

- Dobutamine
- Dopamine
- Milrinone
- Epinephrine
- Norepinephrine, only if administered with dobutamine, dopamine, milrinone, or epinephrine

(b) Has a disease diagnosis of hypertrophic or restrictive cardiomyopathy and is less than one year of age at the time of Status 1B classification

**A candidate's Status 1B classification does not expire.**

**Status 1B by Exception**

A candidate who does not meet criterion (a) or (b) may be classified as Status 1B by exception if the candidate has an urgency and potential for benefit comparable to that of other Status 1B candidates. This classification will be evaluated by the Regional Review Board. If the Regional Review Board denies the request, the attending physician may still classify the candidate as Status 1B. In this instance, the Thoracic Organ Transplantation Committee will review the Regional Review Board's decision and accompanying rationale. The Thoracic Organ Transplantation Committee may refer any case it reviews to the Membership and Professional Standards Committee.

**A candidate's Status 1B classification by exception does not expire.**

**Status 2**

A candidate classified as Status 2 is one who is suitable to receive a thoracic organ transplant, but does not meet the criteria for Status 1A or 1B.

**Status 7**

A candidate classified as Status 7 is temporarily unsuitable to receive a thoracic organ transplant. A Status 7 heart transplant candidate does not accrue waiting time, pursuant to Policy 3.7.9.

**Submission of Status 1A Justification Form**

To classify a candidate as Status 1A, or extend the candidate's Status 1A classification, the candidate's attending physician must submit a completed Heart Status 1A Justification Form to the OPTN Contractor. If a candidate's Status 1A classification expires, the OPTN Contractor will automatically classify a candidate as Status 1B; but, the attending physician must report to the OPTN Contractor the criterion by which the candidate classifies as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not meet criteria for Status 1A or Status 1B.

**Submission of Status 1B Justification Form**

To classify a candidate as Status 1B, the attending physician must submit a completed Heart Status 1B Justification Form to the OPTN Contractor.

**Change in Status 1A or 1B Criterion or Eligibility**

If a change in the candidate's medical condition makes the criterion used to classify a candidate as Status 1A or 1B no longer accurate, the transplant program must report the accurate information to the OPTN Contractor within 24 hours of the change in medical condition.

**3.7.8 Blood Group Matching for Heart Allocation.**

Table 2 presents blood group matching for heart transplant candidates: primary, secondary, and incompatible. A primary blood group match between the candidate and the deceased donor receives higher priority for organ offers than a secondary blood group match.

**Table 2: Blood Group Type Matching for Heart Transplant Candidates**

		<b>Candidate's Blood Group</b>			
		<b><u>O</u></b>	<b><u>A</u></b>	<b><u>B</u></b>	<b><u>AB</u></b>
<b>Donor's Blood Group</b>	<b><u>O</u></b>	<b><u>P</u></b>	<b><u>S</u></b>	<b><u>P</u></b>	<b><u>S</u></b>
	<b><u>A</u></b>	<b><u>I</u></b>	<b><u>P</u></b>	<b><u>I</u></b>	<b><u>P</u></b>
	<b><u>B</u></b>	<b><u>I</u></b>	<b><u>I</u></b>	<b><u>P</u></b>	<b><u>P</u></b>
	<b><u>AB</u></b>	<b><u>I</u></b>	<b><u>I</u></b>	<b><u>I</u></b>	<b><u>P</u></b>

P = primary blood group matching  
S = secondary blood group matching  
I = incompatible blood group matching

**3.7.8.1 Exception to the Primary Blood Group Matching for Candidates Less than One Year of Age**

A potential heart recipient who is less than one year of age **at the time of registration** receives primary blood group matching priority, regardless of how this candidate's blood group matches with the deceased donor's heart.

**3.7.8.2 Exception to the Secondary Blood Group Matching for Candidates at Least One Year of Age**

A potential heart recipient who is at least one year of age and eligible to receive a heart from a donor with an incompatible blood group (see Policy 3.7.8.3) receives secondary blood group matching priority.

**3.7.8.3 Eligibility to Receive an Incompatible Blood Group Heart Offer**

A candidate is eligible to receive a heart with a blood group that is incompatible with the candidate's if the candidate's transplant program reports to the OPTN Contractor the candidate's willingness to receive such a heart offer. To indicate this willingness to the OPTN Contractor, the transplant program must report the candidate's isoheamagglutinin titer level:

- 1) At the time the candidate reports willingness to receive a heart with a blood group that is incompatible with the candidate's; and
- 2) From a blood sample drawn no more than 30 days prior to the date of the last blood sample reported to the OPTN Contractor.

In addition to the reporting requirements listed above, for a candidate who is at least one year of age but became willing to receive heart with a blood group that is incompatible with the candidate's before two years of age, then the transplant program must report to the OPTN Contractor that the candidate's isoheamagglutinin titer level is 1:16 or less. The isoheamagglutinin titer level cannot be due to receipt of treatment 30 days prior to the date of the last blood sample reported to the OPTN Contractor. If the isoheamagglutinin titer level of 1:16 or less is due to treatment, then the candidate is ineligible to receive a blood group incompatible heart.

The transplant program must report to the OPTN Contractor the highest titer value if a laboratory provides more than one Anti-A or Anti-B isohemagglutinin titer value for a given blood sample.

Table 3 details the isohemagglutinin titer level a transplant program must report to the OPTN Contractor for a candidate who is eligible to receive a heart with a blood group that is incompatible to the candidate's.

**Table 3: Isohemagglutinin Titer Level Reporting Requirement for a Candidate Who Received a Heart with a Blood Group that is Incompatible with the Candidate's**

<b><u>If the candidate received a heart with the incompatible blood group of:</u></b>	<b><u>Then, the Transplant Program reports to the OPTN Contractor the candidate's most recent:</u></b>
<u>A</u>	<u>Anti-A isohemagglutinin titer level</u>
<u>B</u>	<u>Anti-B isohemagglutinin titer level</u>
<u>AB</u>	<u>Anti-A and Anti-B isohemagglutinin titer levels</u>

Table 4 details the type of isohemagglutinin titer levels that transplant programs must report for a recipient of a heart with a blood group that is incompatible with the recipient's. For each recipient of a heart with a blood group that is incompatible with the recipient's, the transplant program must report isohemagglutinin titer levels upon:

- Transplant; and
- Graft loss or death, if either occurs within one year of the transplant.

**Table 4: Isohemagglutinin Titer Level Reporting Requirement for a Recipient of a Heart with a Blood Group that is Incompatible with the Recipient's**

<b><u>If the deceased donor's blood group was:</u></b>	<b><u>And the recipient's blood group is:</u></b>	<b><u>Then, the Transplant Program must report the following isohemagglutinin titer level to the OPTN Contractor:</u></b>
<u>A</u>	<u>B or O</u>	<u>Anti-A</u>
<u>B</u>	<u>A or O</u>	<u>Anti-B</u>
<u>AB</u>	<u>A</u>	<u>Anti-B</u>
<u>AB</u>	<u>B</u>	<u>Anti-A</u>
<u>AB</u>	<u>O</u>	<u>Anti-A and Anti-B</u>

**3.7.10.1 Sequence of Pediatric Heart Allocation.** Hearts recovered from pediatric donors must be allocated as follows:

1. Common OPO and Zone A, Status 1A, ABO Primary Pediatric Candidates
2. Common OPO and Zone A, Status 1A, ABO Secondary Pediatric Candidates
3. Common OPO, Status 1A, ABO Primary Adult Candidates
4. Common OPO, Status 1A, ABO Secondary Adult Candidates
5. Common OPO and Zone A, Status 1B, ABO Primary Pediatric Candidates
6. Common OPO and Zone A, Status 1B, ABO Secondary Pediatric Candidates
7. Common OPO, Status 1B, ABO Primary Adult Candidates
8. Common OPO, Status 1B, ABO Secondary Adult Candidates
9. Zone A, Status 1A, ABO Primary Adult Candidates
10. Zone A, Status 1A, ABO Secondary Adult Candidates
11. Zone A, Status 1B, ABO Primary Adult Candidates
12. Zone A, Status 1B, ABO Secondary Adult Candidates
13. Common OPO, Status 2, ABO Primary Pediatric Candidates
14. Common OPO, Status 2, ABO Secondary Pediatric Candidates
15. Common OPO, Status 2, ABO Primary Adult Candidates
16. Common OPO, Status 2, ABO Secondary Adult Candidates
17. Zone B, Status 1A, ABO Primary Pediatric Candidates
18. Zone B, Status 1A, ABO Secondary Pediatric Candidates
19. Zone B, Status 1A, ABO Primary Adult Candidates
20. Zone B, Status 1A, ABO Secondary Adult Candidates
21. Zone B, Status 1B, ABO Primary Pediatric Candidates
22. Zone B, Status 1B, ABO Secondary Pediatric Candidates
23. Zone B, Status 1B, ABO Primary Adult Candidates
24. Zone B, Status 1B, ABO Secondary Adult Candidates
25. Zone A, Status 2, ABO Primary Pediatric Candidates
26. Zone A, Status 2, ABO Secondary Pediatric Candidates
27. Zone A, Status 2, ABO Primary Adult Candidates
28. Zone A, Status 2, ABO Secondary Adult Candidates
29. Zone B, Status 2, ABO Primary Pediatric Candidates
30. Zone B, Status 2, ABO Secondary Pediatric Candidates
31. Zone B, Status 2, ABO Primary Adult Candidates
32. Zone B, Status 2, ABO Secondary Adult Candidates
33. Zone C, Status 1A, ABO Primary Pediatric Candidates
34. Zone C, Status 1A, ABO Secondary Pediatric Candidates
35. Zone C, Status 1A, ABO Primary Adult Candidates
36. Zone C, Status 1A, ABO Secondary Adult Candidates
37. Zone C, Status 1B, ABO Primary Pediatric Candidates
38. Zone C, Status 1B, and ABO Secondary Pediatric Candidates
39. Zone C, Status 1B, ABO Primary Adult Candidates
40. Zone C, Status 1B, ABO Secondary Adult Candidates
41. Zone C, Status 2, ABO Primary Pediatric Candidates
42. Zone C, Status 2, ABO Secondary Pediatric Candidates
43. Zone C, Status 2, ABO Primary Adult Candidates
44. Zone C, Status 2, ABO Secondary Adult Candidates
45. Zone D, Status 1A, ABO Primary Pediatric Candidates
46. Zone D, Status 1A, ABO Secondary Pediatric Candidates
47. Zone D, Status 1A, ABO Primary Adult Candidates
48. Zone D, Status 1A, ABO Secondary Adult Candidates

49. Zone D, Status 1B, ABO Primary Pediatric Candidates
50. Zone D, Status 1B, ABO Secondary Pediatric Candidates
51. Zone D, Status 1B, ABO Primary Adult Candidates
52. Zone D, Status 1B, ABO Secondary Adult Candidates
53. Zone D, Status 2, ABO Primary Pediatric Candidates
54. Zone D, Status 2, ABO Secondary Pediatric Candidates
55. Zone D, Status 2, ABO Primary Adult Candidates
56. Zone D, Status 2, ABO Secondary Adult Candidates
57. Zone E, Status 1A, ABO Primary Pediatric Candidates
58. Zone E, Status 1A, ABO Secondary Pediatric Candidates
59. Zone E, Status 1A, ABO Primary Adult Candidates
60. Zone E, Status 1A, ABO Secondary Adult Candidates
61. Zone E, Status 1B, ABO Primary Pediatric Candidates
62. Zone E, Status 1B, ABO Secondary Pediatric Candidates
63. Zone E, Status 1B, ABO Primary Adult Candidates
64. Zone E, Status 1B, ABO Secondary Adult Candidates
65. Zone E, Status 2, ABO Primary Pediatric Candidates
66. Zone E, Status 2, ABO Secondary Pediatric Candidates
67. Zone E, Status 2, ABO Primary Adult Candidates
68. Zone E, Status 2, ABO Secondary Adult Candidates