

第3回 心臓移植の基準等に関する作業班  
議事次第

日時:平成22年8月11日(水)

17:00~19:00

場所:厚生労働省 専用第27会議室

1. 開 会

2. 議 事

- (1) レシピエント選択基準について
- (2) その他

3. 閉 会

〈配布資料〉

- 資料1 心臓移植希望者(レシピエント)選択基準の見直しについて
- 資料2 心臓移植希望者(レシピエント)選択基準(案)

〈参考資料〉

- 参考資料1 脳死下心臓移植者 移植時データまとめ(2010年6月末現在)  
(社団法人日本臓器移植ネットワーク調べ)
- 参考資料2 心臓移植希望登録者の状況(2010年6月末現在)  
(社団法人日本臓器移植ネットワーク調べ)
- 参考資料3 心臓移植希望者(レシピエント)選択基準(現行)
- 参考資料4 心臓器提供者(ドナー)適応基準(現行)
- 参考資料5 Organ Distribution:Allocation of Thoracic Organs
- 参考資料6 EXECUTIVE SUMMARY OF THE MINUTES  
OPTN/UNOS BOARD OF DIRECTORS MEETING
- 参考資料7 Registry of the International Society for Heart and Lung  
Transplantation:Twelfth Official Pediatric Heart Transplantation  
Report—2009
- 参考資料8 Circulation 2009;119;717-727
- 参考資料9 THE INTERNATIONAL SOCIETY FOR HEART & LUNG  
TRANSPLANTATION  
Heart/Lung Transplant Registry Slides より一部抜粋

## 心臓移植希望者（レシピエント）選択基準の見直しについて

## 【現状等】

- ・ 移植の実効性を担保し、移植機会の公平性が確保されるように、基本的には、医学的適応、組織適合性等の医学的見知から移植希望者選択基準が定められている。
- ・ 平成 22 年 6 月末現在で 169 名の方が心臓移植を希望して（社）日本臓器移植ネットワーク（以下、ネットワーク）に登録をされている。
- ・ 平成 22 年 6 月末現在までに心臓移植を受けた方 69 名中 69 名が医学的緊急度（Status）の Status 1 の状態であった。（社団法人日本臓器移植ネットワーク調べ）

## 【検討の視点】

## ○緊急度（Status）について

- ・ 現在の Status 1 でより緊急度が高いと考えられるのはどのような状態か。
- ・ 現在の緊急度では評価が難しい小児特有の状態はあるか。
- ・ 埋め込み型補助人工心臓を使用している場合と、体外式の補助人工心臓を使用している場合で緊急度を考慮する必要があるか。

## ○年齢について

- ・ 医学的な観点も踏まえ、年齢による優先規定を設けるか。
- ・ 設ける場合に、何歳未満の場合に優先とするか。

## ○血液型について

- ・ O 型の臓器提供者（ドナー）からの臓器の配分をどのように考えるか。（現行の基準「4. その他」の記載を参照）
- ・ 血液型の一致と年齢の優先をどのように考えるか。（例：血液型が一致している成人と血液型が適合している小児の優先順位をどう考えるか）

## ○基準変更に伴う経過措置について

- ・ Status が変更となる待機者の方の待機日数をどのように考えるか。
- ・ 基準の見直しにともなう事務的な手続きについてどの程度の期間を考慮するか。

## 心臓移植希望者（レシピエント）選択基準（案）

### 1. 適合条件

#### (1) ABO式血液型

ABO式血液型の一致 (identical) 及び適合 (compatible) の待機者を候補者とする。

#### (2) 体重 (サイズ)

体重差は-20%~30%であることが望ましい。

ただし、移植希望者（レシピエント）が小児である場合は、この限りではない。

#### (3) 前感作抗体

リンパ球直接交差試験（ダイレクト・クロスマッチテスト）を実施し、抗T細胞抗体が陰性であることを確認する。

パネルテストが陰性の場合、リンパ球直接交差試験（ダイレクト・クロスマッチテスト）は省略することができる。

#### (4) CMV抗体

CMV抗体陰性の移植希望者（レシピエント）に対しては、CMV抗体陰性の臓器提供者（ドナー）が望ましい。

#### (5) HLA型

当面、選択基準にしないが、必ず検査し、登録する。

#### (6) 虚血許容時間

臓器提供者（ドナー）の心臓を摘出してから4時間以内に血流再開することが望ましい。

### 2. 優先順位

適合条件に合致する移植希望者（レシピエント）が複数存在する場合には、優先順位は、以下の順に勘案して決定する。

#### (1) 親族

臓器の移植に関する法律第6条の2の規定に基づき、親族に対し臓器を優先的に提供する意思表示されていた場合には、当該親族を優先する。

## (2) 医学的緊急度

定義： Status 1：次の（ア）から（エ）までの状態のいずれかに該当すること。

（ア）補助人工心臓を装着中の状態

（イ）大動脈内バルーンポンピング（IABP）、経皮的心肺補助装置（PCPS）又は動静脈バイパス（VAB）を装着中の状態

（ウ）人工呼吸施行中の状態

（エ）ICU、CCU等の重症室に收容され、かつ、カテコラミン等の強心薬の持続的な点滴投与を行っている状態

\* カテコラミン等の強心薬にはフォスフォディエステラーゼ阻害薬なども含まれる

\* ただし、小児（18歳未満）の場合は、重症室に收容されていない場合であつて、カテコラミン等の強心薬の持続的な点滴投与を行っている状態も含まれる

Status 2：待機中の患者で、上記以外の状態

Status 3：Status 1、Status 2で待機中、除外条件（感染症等）を有する状態のため一時的に待機リストから削除された状態

Status 1、Status 2の順に優先する。（3. の具体的選択方法を参照）。また、Status 3への変更が登録された時点で、選択対象から外れる。除外条件がなくなり、Status 1又はStatus 2へ再登録された時点から、移植希望者（レシピエント）として選択対象となる。

## (3) 年齢

臓器提供者（ドナー）が18歳未満の場合には、18歳未満の移植希望者（レシピエント）を優先する（3. の具体的選択方法を参照）。

## (4) ABO式血液型

ABO式血液型の一致（identical）する者を適合（compatible）する者より優先する（3. の具体的選択方法を参照）。

## (5) 待機期間

以上の条件が全て同一の移植希望者（レシピエント）が複数存在する場合は、待機期間の長い者を優先する。

○Status 1の移植希望者（レシピエント）間では、待機期間はStatus 1の延べ日数とする。

○Status 2の移植希望者（レシピエント）間では、待機期間は登録日からの延べ日数とする。

### 3. 具体的選択方法

#### (1) 臓器提供者（ドナー）が18歳以上の場合

順位*	医学的緊急度	ABO式血液型
1	Status 1	一致
2		適合
3	Status 2	一致
4		適合

\* 同順位内に複数名の移植希望者（レシピエント）が存在する場合には待機期間の長い者を優先する。

#### (2) 臓器提供者（ドナー）が18歳未満の場合

順位*	医学的緊急度	年齢	ABO式血液型
1	Status 1	<u>18歳未満</u>	一致
2			適合
3		<u>18歳以上</u>	一致
4			適合
5	Status 2	<u>18歳未満</u>	一致
6			適合
7		<u>18歳以上</u>	一致
8			適合

\* 同順位内に複数名の移植希望者（レシピエント）が存在する場合には待機期間の長い者を優先する。

#### (2) ネットワークが組織的にも機能的にもブロック化された場合

→ネットワークにより一元的に分配が可能であり、現時点では削除してもよいのではないか。

### 4. その他

将来、Status 1の移植希望者（レシピエント）が増加すると、O型の臓器提供者（ドナー）からの臓器が順位2の移植希望者（レシピエント）に配分され、Status 2の移植希望者（レシピエント）に配分されない事態が生じることが予想される。この場合はブロック制の導入を含めて、選択基準の見直しをすることとする。

## 脳死下心臓移植者 移植時データまとめ (2010年6月末現在)

### 1. 移植時の医学的緊急度

緊急度	人数
Status1	69
Status2	1

※ Status2は心肺同時移植の方

### 2. 移植時緊急度 Status1 対象者の該当条件

Status1条件	該当者(重複有)
(ア) 補助人工心臓	52
(イ) IABP	2
(ウ) 人工呼吸器	2
(エ) カテコラミン&ICU/CCU入室	31

<心臓>

2010.6.30現在

移植希望者数 169 名

【血液型】

A	76
B	39
O	45
AB	9
計	169

【性別】

男	121
女	48
計	169

【年代】

0-9歳	1
10-19歳	6
20-29歳	37
30-39歳	47
40-49歳	41
50-59歳	33
60-69歳	4
70歳-	0
計	169

15歳未満	2
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【原疾患】

拡張型心筋症	97
拡張相の肥大型心筋症	22
拘束型心筋症	2
虚血性心疾患	15
弁膜症	2
先天性心疾患	5
再移植	1
その他	25
計	169

【医学的緊急度】

Status1	109
Status2	48
Status3	12
計	169

【待機期間】

1年未満	51
1年以上2年未満	51
2年以上3年未満	21
3年以上4年未満	18
4年以上5年未満	6
5年以上	22
計	169

## 心臓移植希望者（レシピエント）選択基準

### 1. 適合条件

#### (1) ABO式血液型

ABO式血液型の一致 (identical) 及び適合 (compatible) の待機者を候補者とする。

#### (2) 体重 (サイズ)

体重差は-20%~30%であることが望ましい。

ただし、移植希望者（レシピエント）が小児である場合は、この限りではない。

#### (3) 前感作抗体

リンパ球直接交差試験（ダイレクト・クロスマッチテスト）を実施し、抗T細胞抗体が陰性であることを確認する。

パネルテストが陰性の場合、リンパ球直接交差試験（ダイレクト・クロスマッチテスト）は省略することができる。

#### (4) CMV抗体

CMV抗体陰性の移植希望者（レシピエント）に対しては、CMV抗体陰性の臓器提供者（ドナー）が望ましい。

#### (5) HLA型

当面、選択基準にしないが、必ず検査し、登録する。

#### (6) 虚血許容時間

臓器提供者（ドナー）の心臓を摘出してから4時間以内に血流再開することが望ましい。

### 2. 優先順位

適合条件に合致する移植希望者（レシピエント）が複数存在する場合には、優先順位は、以下の順に勘案して決定する。

#### (1) 親族

臓器の移植に関する法律第6条の2の規定に基づき、親族に対し臓器を優先的に提供する意思表示されていた場合には、当該親族を優先する。



## (2) 医学的緊急度

定義： Status 1：次の（ア）から（エ）までの状態のいずれかに該当すること。

（ア）補助人工心臓を必要とする状態

（イ）大動脈内バルーンポンピング（IABP）を必要とする状態

（ウ）人工呼吸を必要とする状態

（エ）ICU、CCU等の重症室に収容され、かつ、カテコラミン等の強心薬の持続的な点滴投与が必要な状態

\* カテコラミン等の強心薬にはフォスフォディエステラーゼ阻害薬なども含まれる

Status 2：待機中の患者で、上記以外の状態

Status 3：Status 1、Status 2で待機中、除外条件（感染症等）を有する状態のため一時的に待機リストから削除された状態

原則として Status 1を優先する（後述する具体的選択法を参照）。また、Status 3への変更が登録された時点で、選択対象から外れる。除外条件がなくなり、Status 1又は Status 2へ再登録された時点から、移植希望者（レシピエント）として選択対象となる。

## (3) ABO式血液型

一致を原則とするが、緊急性の高い Status 1の移植希望者（レシピエント）がない場合や他に一致する移植希望者（レシピエント）がない場合には、適合者に配分する（後述する具体的選択法を参照）。

## (4) 待機期間

以上の条件が全て同一の移植希望者（レシピエント）が複数存在する場合は、待機期間の長い者を優先する。

○Status 1の移植希望者（レシピエント）間では、待機期間は Status 1の延べ日数とする。

○Status 2の移植希望者（レシピエント）間では、待機期間は登録日からの延べ日数とする。

## 3. 具体的選択方法

### (1) ネットワークがブロック化されていない場合

順位*	医学的緊急度	ABO式血液型
1	Status 1	一致
2	Status 1	適合
3	Status 2	一致
4	Status 2	適合

\*同順位内に複数名の移植希望者（レシピエント）が存在する場合には待機期間の長い者を優先する。

(2) ネットワークが組織的にも機能的にもブロック化された場合

順位*	距離	医学的緊急度	ABO式血液型
1	ブロック内	Status 1	一致
2	ブロック内	Status 1	適合
3	ブロック内	Status 2	一致
4	他ブロック	Status 1	一致
5	他ブロック	Status 1	適合
6	ブロック内	Status 2	適合
7	他ブロック	Status 2	一致
8	他ブロック	Status 2	適合

\*同順位内に複数名の移植希望者（レシピエント）が存在する場合には待機期間の長い者を優先する。

4. その他

将来、Status 1の移植希望者（レシピエント）が増加すると、O型の臓器提供者（ドナー）からの臓器が順位2の移植希望者（レシピエント）に配分され、Status 2の移植希望者（レシピエント）に配分されない事態が生じることが予想される。この場合はブロック制の再考を含めて、選択基準の見直しをすることとする。

## ＜心臓＞臓器提供者（ドナー）適応基準

1. 以下の疾患又は状態を伴わないこととする。
  - (1) 全身性の活動性感染症
  - (2) HIV抗体、HTLV-1抗体、HBs抗原、HCV抗体などが陽性
  - (3) クロイツフェルト・ヤコブ病及びその疑い
  - (4) 悪性腫瘍（原発性脳腫瘍及び治癒したと考えられるものを除く。）
  
2. 以下の疾患又は状態を伴う場合には、移植の適応を慎重に検討する。
  - (1) 心疾患の既往
  - (2) 心電図、心エコー図などによる心疾患の所見
  - (3) 大量のカテコラミン剤の使用  
(例：ドパミン  $10\mu\text{g}/\text{kg}/\text{min}$  にても血行動態の維持が困難な場合)
  
3. 年齢：50歳以下が望ましい。

付記 上記の基準は適宜見直されること。

3.7 **ALLOCATION OF THORACIC ORGANS.** This policy describes how thoracic organs (hearts, heart-lung combinations, single and double lungs) are to be allocated to candidates awaiting a thoracic organ transplant.

3.7.1 **Exceptions.** Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances)), and 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

3.7.1.1 **Exception for Sensitized Candidates.** The transplant surgeon or physician for a candidate awaiting thoracic organ transplantation may determine that the candidate is "sensitized" such that the candidate's antibodies would react adversely to certain donor cell antigens. It is permissible not to use the allocation policies set forth in Policy 3.7 for allocation of a particular thoracic organ when all thoracic organ transplant centers within an OPO and the OPO agree to allocate the thoracic organ to a sensitized candidate because results of a crossmatch between the blood serum of that candidate and cells of the thoracic organ donor are negative (i.e., the candidate and thoracic organ donor are compatible). The level of sensitization at which a candidate may qualify for this exception is left to the discretion of the listing transplant center, and subject to agreement among all thoracic organ transplant centers within an OPO and the OPO. Sensitization is not a qualifying criterion for assigning a candidate to a heart status category as described in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status).

3.7.2 **Geographic Sequence of Thoracic Organ Allocation.** Thoracic organs are to be allocated locally first, then within the following zones in the sequence described in Policy 3.7.10 and Policy 3.7.11. Five zones will be delineated by concentric circles of 500, 1,000, and 1,500 and 2,500 nautical mile radii with the donor hospital at the center. Zone A will extend to all transplant centers which are within 500 miles from the donor hospital but which are not in the local area of the donor hospital. Zone B will extend to all transplant centers that are at least 500 miles from the donor hospital but not more than 1,000 miles from the donor hospital. Zone C will extend to all transplant centers that are at least 1,000 miles from the donor hospital but not more than 1,500 miles from the donor hospital. Zone D will extend to all transplant centers that are located beyond 1,500 miles from the donor hospital, but not more than 2,500 miles from the donor hospital. Zone E will extend to all transplant centers that are located beyond 2,500 miles from the donor hospital.

3.7.3 **Adult Candidate Status.** Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows:

Status Definition

IA A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A(b) candidates) and has at least one of the following devices or therapies in place:

(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:

(i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not

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- required.
- (ii) total artificial heart;
- (iii) intra-aortic balloon pump; or
- (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

- (b) Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates). Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.
- (c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.
- (d) Continuous infusion of a single high-dose intravenous inotrope (e.g., dobutamine  $\geq 7.5$  mcg/kg/min, or milrinone  $\geq .50$  mcg/kg/min), or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures; Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate.

A candidate who does not meet the criteria for Status 1A may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. The justification must be reviewed and approved by the Regional Review. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. A candidate's listing under this exceptional provision is valid for 14 days.

Any further extension of the Status 1A listing under this criterion requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee.

For all adult candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received by on UNet<sup>SM</sup> in order to list a candidate

as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.3. Candidates listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNet<sup>SM</sup> by an attending physician within the time frames described in the definitions of status 1A(a)-(d) above.

- 1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:
- (aa) left and/or right ventricular assist device implanted; or
  - (bb) continuous infusion of intravenous inotropes.

For all adult candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate within one working day of a candidate's listing as Status 1B. A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.

- 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.
- 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.

- 3.7.4 **Pediatric Candidate Status.** Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is less than 18 years of age at the time of listing as follows: Pediatric heart transplant candidates who remain on the Waiting List at the time of their 18<sup>th</sup> birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in Policy 3.7.4.

Status Definition

- 1A A candidate listed as Status 1A meets at least one of the following criteria:
- (a) Requires assistance with a ventilator;
  - (b) Requires assistance with a mechanical assist device (e.g., ECMO);
  - (c) Requires assistance with a balloon pump;
  - (d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

- (e) Requires infusion of high dose (*e.g.*, dobutamine  $\geq 7.5$  mcg/kg/min or milrinone  $\geq 50$  mcg/kg/min) or multiple inotropes (*e.g.*, addition of dopamine at  $\geq 5$  mcg/kg/min); or
- (f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable Regional Review Board.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

For all pediatric candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. Candidates who are listed as Status 1A will automatically revert back to Status 1B after 14 days unless these candidates are re-listed on UNet<sup>SM</sup> as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above

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

- (a) Requires infusion of low dose single inotropes (*e.g.*, dobutamine or dopamine  $\leq 7.5$  mcg/kg/min);
- (b) Less than six months old and does not meet the criteria for Status 1A; or
- (c) Growth failure *i.e.*,  $+ 5^{\text{th}}$  percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either  $< 5^{\text{th}}$  percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate's growth at two different times, second, calculating the candidate's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.*, (candidate's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

For all pediatric candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate as Status 1B. A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as

defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.

- 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.
- 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.

**3.7.5 Allocation of Pediatric Donor Hearts to Pediatric Heart Candidates.** Within each heart status, a heart retrieved from a pediatric organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, a pediatric organ donor is defined as an individual who is less than 18 years of age.

**3.7.6 Lung Allocation.** Candidates are assigned priority in lung allocation as follows:

**3.7.6.1 Candidates Age 12 and Older.** Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.



**Table 1**  
**Factors Used to Predict Risk of Death on the Lung Transplant Waitlist**

1.	Forced vital capacity (FVC)
2.	Pulmonary artery (PA) systolic pressure (Groups A, C, and D <sup>+</sup> – see 3.7.6.1.a)
3.	O <sub>2</sub> required at rest (Groups A, C, and D <sup>+</sup> – see 3.7.6.1.a)
4.	Age
5.	Body mass index (BMI)
6.	Diabetes
7.	Functional Status
8.	Six-minute walk distance
9.	Continuous mechanical ventilation
10.	Diagnosis
11.	PCO <sub>2</sub> (see 3.7.6.1.b) <u>Bilirubin (current bilirubin – all <u>g</u>Groups; change in bilirubin –</u>
12.	<u>Group B; see 3.7.6.1.c)</u>

**Table 2**  
**Factors that Predict Survival after Lung Transplant**

1.	FVC (Groups B and D – see 3.7.6.1.a)
2.	PCW pressure $\geq 20$ (Group D – see 3.7.6.1.a)
3.	Continuous mechanical ventilation
4.	Age
5.	Serum Creatinine
6.	Functional Status
7.	Diagnosis

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.

As an example, assume that a donor lung is available, and both Candidate X and Candidate Y are on the Waiting List. Taking into account all diagnostic and prognostic factors, Candidate X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Candidate X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Candidate Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize candidates based on the difference between each candidate’s transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

**Table 3**  
**Example Illustrating the LAS Calculation**

Parts of the Score Equation	Candidate X	Candidate Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
<b>e. Lung Allocation Score</b>	<b>74.3</b>	<b>78.0</b>

In the example here, Candidate X's raw allocation score would be 84.1 and Candidate Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by candidates and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Candidate X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Candidate Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Candidate Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Candidate X.

a. Lung Disease Diagnosis Groups

The following are some of the diagnoses included in groups A, B, C, and D.

(i) *Group A*

Includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure  $\leq 30$  mmHg

(ii) *Group B*

Includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases

(iii) *Group C*

Includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia

(iv) *Group D*

Includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure  $> 30$  mmHg, and obliterative bronchiolitis (non-retransplant)

b. PCO<sub>2</sub> in the Lung Allocation Score

UNet<sup>SM</sup> will use two measures of PCO<sub>2</sub> in a candidate's lung allocation score calculation: current PCO<sub>2</sub>, and change in PCO<sub>2</sub>. There are two types of PCO<sub>2</sub> change calculations: "threshold change" and "threshold change maintenance." The following explanations (i-vi) and illustrations (Figures 1-3) detail how UNet<sup>SM</sup> uses PCO<sub>2</sub> in the lung allocation score.

(i) *Use of Arterial, Venous, or Capillary PCO<sub>2</sub> Values*

In UNet<sup>SM</sup>, a center may enter a PCO<sub>2</sub> value from an arterial, venous, or capillary blood gas test. UNet<sup>SM</sup> will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNet<sup>SM</sup> will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNet<sup>SM</sup> will use the PCO<sub>2</sub> value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet<sup>SM</sup> will use the arterial value in the lung allocation score calculation.

(ii) *Definition of Current PCO<sub>2</sub>*

Current PCO<sub>2</sub> is the PCO<sub>2</sub> value with the most recent test date entered in UNet<sup>SM</sup>.

(iii) *Expiration of Current PCO<sub>2</sub> Value*

UNet<sup>SM</sup> will evaluate a current PCO<sub>2</sub> value as expired according to Policy 3.7.6.3.2.

(iv) *Use of Normal Clinical Value for Current PCO<sub>2</sub>*

The normal clinical value of PCO<sub>2</sub> is 40 mmHg. UNet<sup>SM</sup> will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO<sub>2</sub> is less than 40 mmHg, missing, or expired.

(v) *PCO<sub>2</sub> Values Used in the Change Calculations*

There are two types of PCO<sub>2</sub> change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO<sub>2</sub> change is 15% or higher. In this calculation, UNet<sup>SM</sup> will use highest and lowest values of PCO<sub>2</sub>. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet<sup>SM</sup> will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet<sup>SM</sup> will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is  $[(\text{highest PCO}_2 - \text{lowest PCO}_2) / \text{lowest PCO}_2]$

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO<sub>2</sub> value must be at least 15% higher than the lowest value used in the threshold change

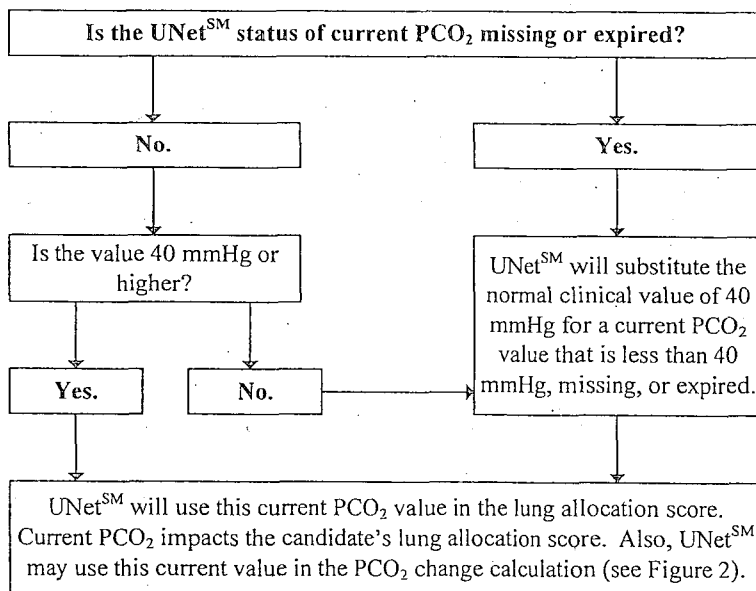
calculation. The equation for threshold change maintenance is  $[(\text{current PCO}_2 - \text{lowest PCO}_2) / \text{lowest PCO}_2]$ .

UNet<sup>SM</sup> will perform the threshold change maintenance calculation either when the current PCO<sub>2</sub> value expires (Policy 3.7.6.3.2) or a new current PCO<sub>2</sub> value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO<sub>2</sub> value can be the highest one that was used in the threshold change calculation. If a current PCO<sub>2</sub> value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO<sub>2</sub> value expires, UNet<sup>SM</sup> will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% higher than the lowest value in the threshold change calculation.

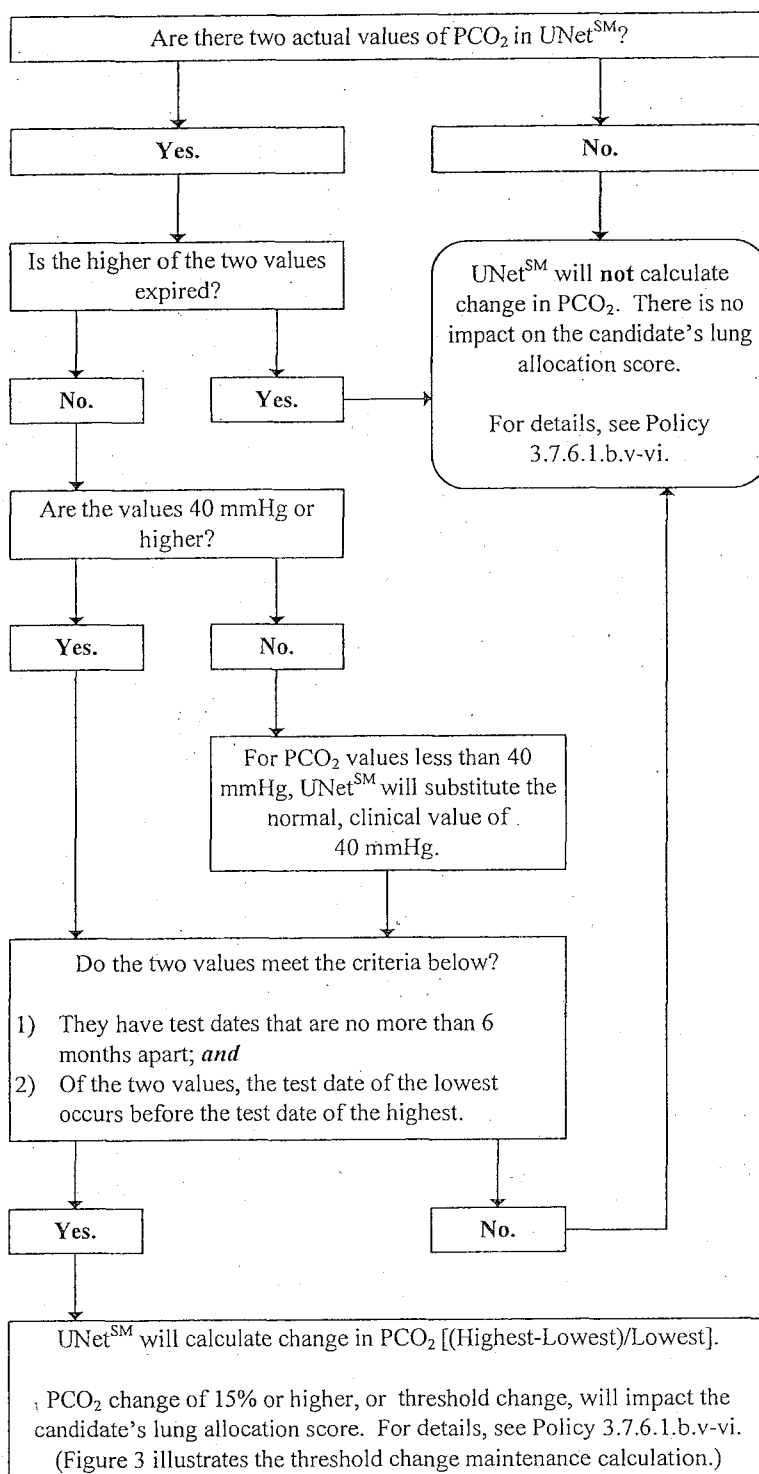
If a center enters a new current PCO<sub>2</sub> value for a candidate who has lost the impact from threshold change, UNet<sup>SM</sup> will perform the threshold change maintenance calculation. If the new current PCO<sub>2</sub> value is at least 15% higher than the lowest value used in the threshold change calculation, UNet<sup>SM</sup> will *reapply* the impact from threshold change to the candidate's lung allocation score.

- (vi) *Impact of PCO<sub>2</sub> Threshold Change in the Lung Allocation Score*  
A change in PCO<sub>2</sub> that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO<sub>2</sub> is at least 15% higher than the lowest value used in the threshold change calculation.

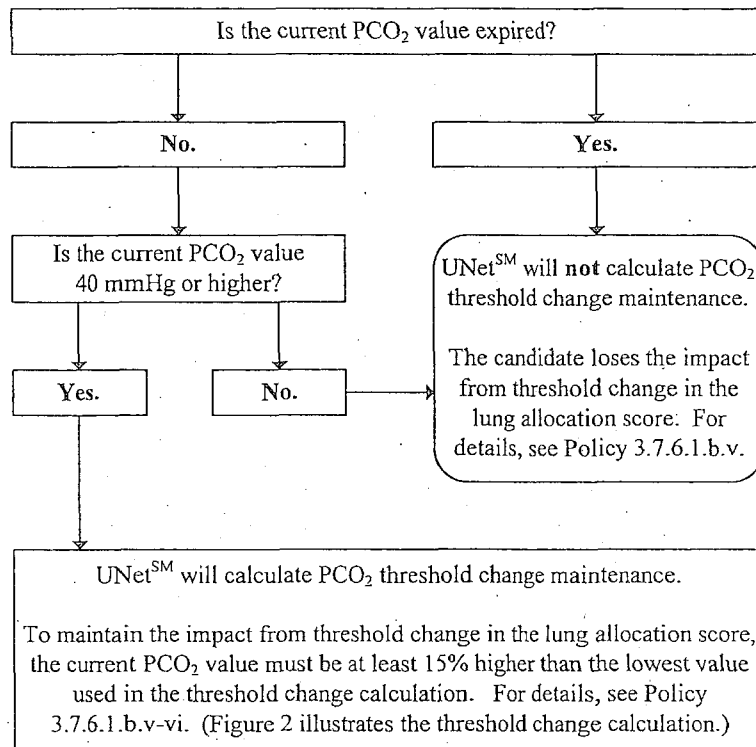
**Figure 1**  
**Use of Current PCO<sub>2</sub> in the Lung Allocation Score**



**Figure 2**  
**PCO<sub>2</sub> Threshold Change Calculation**



**Figure 3**  
**PCO<sub>2</sub> Threshold Change Maintenance Calculation**



c. Bilirubin in the Lung Allocation Score

UNet<sup>SM</sup> will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNet<sup>SM</sup> uses bilirubin in the lung allocation score.

(i) Definition of Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet<sup>SM</sup>. UNet<sup>SM</sup> will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

(ii) Expiration of Current Bilirubin Value

UNet<sup>SM</sup> will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.2.

(iii) Use of Normal Clinical Value for Current Bilirubin

The normal clinical value of current bilirubin is 0.7 mg/dL. UNet<sup>SM</sup> will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

(iv) Bilirubin Values Used in the Change Calculations (Group B Only)

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet<sup>SM</sup> will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet<sup>SM</sup> will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet<sup>SM</sup> will substitute the normal clinical value of 0.7 mg/dL, before calculating change. The equation for threshold change is [(highest bilirubin – lowest bilirubin)/lowest bilirubin].

The threshold change maintenance calculation occurs after the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is [(current bilirubin – lowest bilirubin)/lowest bilirubin].

UNet<sup>SM</sup> will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3.2) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet<sup>SM</sup> will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% higher than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNet<sup>SM</sup> will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the threshold change calculation, UNet<sup>SM</sup> will *reapply* the impact from threshold change to the candidate's lung allocation score.

(v) *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*

A change in bilirubin that is 50% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

**NOTE:** *The amendments to Policy 3.7.6.1.c (Bilirubin in the Lung Allocation Score) shall be implemented pending Executive Committee approval of the related implementation plan. (Approved at the June 2009 Board of Directors Meeting.)*

**3.7.6.2 Candidates Age 0 - 11.** Candidates 0 – 11 years old are assigned priority for lung offers based upon waiting time, according to the status categories UNet<sup>SM</sup> ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each status priority, UNet<sup>SM</sup> will rank

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candidates will be ranked by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority Status 1, UNet<sup>SM</sup> will only consider the most current period of time a candidate has spent as Priority 1, i.e. UNet<sup>SM</sup> will not tally the time waiting during multiple Priority 1 periods. candidates will be ranked in descending order according to the length of time waiting at that status. For Priority Status 2 candidates, and if there is ever a tie among Priority 1 candidates, UNet<sup>SM</sup> will use these candidates' total waiting time to determine the order for receiving lung offers. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive. total active waiting time (defined for this purpose as beginning when the candidate was added to the waiting list and ending when the lung match run was generated) will be used to rank candidates on the match run.

A program may update clinical data used to justify a candidate's status priority may be updated at any time a program it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a programs must update every candidate variable each qualifying criterion, except those candidate variables that which is are obtained only by heart catheterization, for Status 1 candidates, at least once every in each six months period following the candidate's registration after initial listing on the lung waiting list Waitlist<sup>SM</sup>. If at any time, more than six months have elapsed since the last six month "anniversary" date of the candidate's initial listing without an update, without data updates after the candidate's last six-month "anniversary" of his or her Waitlist<sup>SM</sup> registration, then the candidate's status Priority 1 will automatically revert to Status Priority 2. UNet<sup>SM</sup> will assess the currency of lung variables for each candidate on every six-month "anniversary" date. (For example, if a candidate is first registered on the Waitlist<sup>SM</sup> on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet<sup>SM</sup> will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet<sup>SM</sup> will reassess the currency of the lung variables on July 1, 2012, and then any variables with test dates that are on or after January 1, 2012 would be considered current.)

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total waiting time is the amount of time spent waiting as a Status 1 and Status 2.

**Status Priority 1:** Candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous mechanical ventilation; *or*,
  - Requiring supplemental oxygen delivered by any means to achieve  $FiO_2$  greater than 50% in order to maintain oxygen saturation levels greater than 90%; *or*,
  - Having an arterial or capillary  $PCO_2$  greater than 50 mmHg, or a venous  $PCO_2$  greater than 56mmHg.
  
- **Pulmonary hypertension, defined as:**
  - Having pulmonary vein stenosis involving 3 or more vessels; *or*
  - Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M<sup>2</sup>, recurrent syncope, or hemoptysis

Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet<sup>SM</sup>. Transplant centers must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit



~~an exception request to the Lung Review Board for prospective consideration, as described below.~~

~~or~~

~~o Having pulmonary vein stenosis involving 3 or more vessels.~~

• ~~Exceptional cases by prospective submission to~~ **An exception case approved by the Lung Review Board;**

o In its review of exception requests, the Lung Review Board will follow the prospective review process described in Policy 3.7.6.4 (Lung Candidates with Exceptional Cases).

**Status 2:** Candidates who do not meet the criteria for ~~Status Priority 1~~ must be listed ~~Status~~ as Priority 2.

*NOTE: The amendments to Policy 3.7.6.2 (Candidates Age 0-11) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Double lines and double strikeouts were added and approved at the June 23, 2009 Board of Directors Meeting.)*

*NOTE: The amendments to Policy 3.7.6.2 (Candidates Age 0-11) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Approved at the June 20, 2008 Board of Directors Meeting.)*

**3.7.6.3 Candidate Variables in UNet<sup>SM</sup>.** Entry into UNet<sup>SM</sup> of candidate clinical data responding to the variables shown in Tables 1 and 2 above, as they may be amended from time to time, is required when listing a candidate for lung transplantation. Diagnosis, birthdate (used to calculate age), height, and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a Lung Allocation Score of zero, if the Functional Status class or assisted ventilation variable is missing at any time. If pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for the missing pulmonary pressure variable. (A default value of 20 mm/Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm/Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm/Hg will be assigned for missing pulmonary artery mean pressure.) The default values for pulmonary pressures will also be used in the calculation of Lung Allocation Scores for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), will be selected for the candidate. Programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board to determine whether the estimated values are appropriate and whether further action is warranted. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to the procedures set forth in Policy 3.7.6.4.

**3.7.6.3.1 Candidate Variables in UNet<sup>SM</sup> upon Implementation of Lung Allocation Scores Described in Policy 3.7.6.** Candidates registered on the Lung Waiting List at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 with no or incomplete clinical data will receive the Least Beneficial Value or the default pulmonary pressure value for each incomplete variable or a Lung Allocation Score of zero, as described in Policy 3.7.6 above.

**3.7.6.3.2 Updating Candidate Variables.** Programs may update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update every candidate variable, except those candidate variables that are obtainable only by heart catheterization, for each candidate at least once every six months beginning on the date of initial listing on the lung waitlist. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing, without an update, then the variable will be considered expired. (For example, if a candidate was first registered on the waitlist on January 1, 2005, and the most recent six-month "anniversary" is January 1, 2006, then any variables older than July 1, 2005, will be considered expired.)

If the Functional Status or assisted ventilation variable is expired, then the candidate will receive a Lung Allocation Score of zero. If any other candidate variable, excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure, is expired, then the candidate will receive the Least Beneficial Value for that variable. The frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) will be left to the discretion of the transplant center. Actual values or estimated values for pulmonary pressures will be valid until they are either updated with a new actual value or a new estimated value is entered pursuant to Policy 3.7.6.4.

**3.7.6.4 Lung Candidates With Exceptional Cases.** Special cases require prospective review by the Lung Review Board. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant center will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to the OPTN contractor. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that the contractor sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the center may choose to appeal the decision for reconsideration by the Lung Review Board. The center will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that the contractor sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.

Should the Lung Review Board deny a transplant center's initial request or appealed request for an estimated value or a specific Lung Allocation Score, the transplant center has the option to override the decision of the LRB. If the transplant center elects to override the decision of the Lung Review Board, then the request or appeal will be automatically referred to the Thoracic Organ Transplantation Committee for review; this review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

Estimated values will remain valid until an actual value is entered in the system or a new estimated value is entered pursuant to the procedures described in this

policy. A diagnosis that has been approved by the Lung Review Board or the Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. Lung Allocation Scores will remain valid for six (6) months from the entry date (or the candidate's twelfth birthday, whichever occurs later). If the candidate continues to be on the Waiting List six months after the entry date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is entered pursuant to the procedures described in this policy or the center chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung Review Board.

**3.7.7 Allocation of Thoracic Organs to Heart-Lung Candidates.** When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart. Heart-lung candidates shall use the ABO matching requirements described in Policy 3.7.8 when they are included in the heart match run results. Heart-lung candidates shall use the ABO matching requirements described in policy 3.7.8.2 when they are included in the lung match run results.

**3.7.8 ABO Typing for Heart Allocation.** Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

- (i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;
- (ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;
- (iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;
- (iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.
- (v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.
- (vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

- (i) Candidate is *in utero*;
- (ii) Candidate is less than 1 year of age, and meets all of the following:
  - a. Listed at Status 1A or 1B, and

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- b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNet<sup>SM</sup>.
- (iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:
  - a. Is ~~l~~isted prior to age 2;
  - b. Is ~~l~~isted at Status 1A or 1B;
  - c. Has ~~C~~urrent isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNet<sup>SM</sup>; and,
  - d. Has *not* received treatments (such as plasmapheresis or transfusions) within the prior 30 days that could potentially alter spontaneously produced titer values may have reduced titer values to 1:4 or less.

~~Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in Policy 3.7.10, by heart status category to Status 1 pediatric heart candidates less than one year up to less than two years of age at time of listing identified as being compatible with any eligible to receive a heart from any blood type donor. (typically based on having Eligibility is defined as age  $\leq$  6 months 1 year old or recipient candidate isohemagglutinin titers less than or equal to 1:4 for A and/or B blood type antigens) for infants  $\geq$  6 months old  $\geq$  1 year old who have a blood type that is incompatible with the donor's blood type if the candidate is been listed with the blood type "Z" designation as willing to accept a heart from a donor of any blood type. The isohemagglutinin titer used for recipient selection modifiers, such as plasmapheresis or transfusions, within 30 days. When isohemagglutinin titers in recipient candidates  $\geq$  6 months old  $\geq$  1 year old cannot be accurately determined due to modifiers received within 30 days that could potentially manipulate titer values, then status Z listing the candidate shall not be designated as eligible to accept donor hearts of any blood type under this policy used. Following allocation for born pediatric candidates who are eligible to accept donor hearts of any blood type "Z" incompatible pediatric heart candidates, less than one year of age, hearts will be allocated, locally first and then within zones in the sequence described in Policy 3.7.10, to patients listed *in utero*.~~

**NOTE #2** *Additional amendments) (indicated by double strikethrough and double underline formatting) to Policy 3.7.8 (ABO Typing for Heart Allocation) shall be approved and implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. Approved by the Executive Committee on August 10, 2009)*

**NOTE #1:** *The amendments to Policy 3.7.8 (ABO Typing for Heart Allocation) shall be approved and implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Approved at the Executive Committee Meeting on December 18, 2007). )*

**3.7.8.1 Heart Allocation to Pediatric Candidates Less Than 2 Years of Age Willing Eligible to Accept a Donor Heart of Any Blood Type.** A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

Anti-A and/or Anti-B titers must be reported:

- (i) At time of listing (except for *in utero* candidates);
- (ii) Every 30 days after listing (all eligible born candidates);
- (iii) At transplant; and
- (iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts).

Listing and transplant outcomes for candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.

~~**Heart Allocation to Pediatric Candidates Registered Under Blood Type "Z". Heart Allocation to Pediatric Candidates < 2 Years of Age Willing to Accept a Donor Heart of Any Blood Type.** For pediatric candidates less than two years of age at time of listing who meet the eligibility requirements set forth in Policy 3.7.8, including *in utero* candidates for whom blood type is unknown, centers may specify on the Waiting List those candidates who will accept a heart from a donor of any blood type; the blood type "Z" designation may be added as a suffix to the actual blood type (e.g., "AZ") of a pediatric patient less than one year up to less than two years of age, or used alone if actual blood type is not known for *in utero* candidates. Patients older than two years of age may be listed with the type "Z" designation suffix upon an application by his/her transplant physician(s) providing justification to the applicable Regional Review Board. Timing of the review of these cases shall be prospective. Anti-A and anti-B titers shall must be reported at the times of listing, (except for *in utero* candidates), monthly after listing (all eligible candidates), at transplant and in the event of graft loss or death within one year after transplant (for candidates transplanted with other than blood type identical or compatible donor hearts). Listing and transplant outcomes for status Z candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates with the blood type Z designation for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.~~

**NOTE:** *The amendments to Policy 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type ABO Typing for Heart Allocation) shall be approved and implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Approved at the Executive Committee Meeting on December 18, 2007)*

**3.7.8.2 ABO Typing for Lung Allocation.** Candidates who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated thoracic organs before candidates who have a compatible (but not identical) blood type with that of the donor and are awaiting an isolated lung transplant

**3.7.9 Time Waiting for Thoracic Organ Candidates.** Calculation of the time a candidate has been waiting for a thoracic organ transplant begins with the date and time the candidate is first registered as active on the Waiting List. Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age). When time waiting is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status/priority category. Where applicable, waiting time accrued by a candidate for a single thoracic organ transplant (heart or single lung) while waiting on the Waiting List also may be accrued for a second thoracic organ, when it is determined that the candidate requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a candidate for a multiple thoracic organ transplant while waiting on the Waiting List may be transferred to the Waiting List for a single thoracic organ transplant.

*NOTE: The amendments to Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates) (stricken text; double-underlined text) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup> of Policy 3.7.6.2 (Candidates Age 0-11). (Approved at the June 22-23, 2009 Board of Directors Meeting.)*

**3.7.9.1 Waiting Time Accrual for Heart Candidates.** Candidates listed as a Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation if the candidate is upgraded to a higher status. For example, a candidate who is listed as a Status 2 for 3 months and then is upgraded to a Status 1A for one week will accrue one week of waiting time as a Status 1A. If the candidate is downgraded to a Status 2 for another 3 weeks, then the candidate will have 4 months of total accrued time. If the candidate subsequently is upgraded for another week as a Status 1A, then the candidate's Status 1A waiting time will be 2 weeks.

**3.7.9.2 Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6** ~~Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 and thereafter will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued.~~

*\*\* BOLD language that appears in Policy 3.7.9.2 was approved by the Executive Committee on March 11, 2005, and was implemented on May 4, 2005.*

In the event that multiple candidates receive identical computed Lung Allocation Scores greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each candidate's most recent update in UNet<sup>SM</sup> by the member, of variables used in calculation of the Lung Allocation Score. (For example, if Candidate A and Candidate B have an identical Lung Allocation Score and identical priority for a lung offer, and Candidate A's data variables were most recently updated by the transplant center on May 1, 2005, and Candidate B's data variables were most recently updated by the transplant center on June 1, 2005, then Candidate A would receive higher priority for the lung offer because his most recent data update by the transplant center occurred first and the same set of data variables has been used to calculate Candidate A's Lung Allocation Score for the longest amount of time.)

In the event that multiple candidates receive identical assigned Lung Allocation Scores pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent approval of that Lung Allocation Score by the Lung Review Board was entered in UNet<sup>SM</sup> (For example, if Candidate X and Candidate Y have identical Lung Allocation Scores assigned to them by the Lung Review Board and identical priority for a lung offer, and the approval for Candidate X's score was entered in UNet<sup>SM</sup> on June 1, 2005, and the approval for Candidate Y's score was entered in UNet<sup>SM</sup> on July 1, 2005, then Candidate X would receive

higher priority for the lung offer because his most recent Lung Allocation Score was approved and entered in UNet<sup>SM</sup> first.)

Candidates that receive a Lung Allocation Score of zero due to missing or expired candidate variables as described in Policy 3.7.6.3 will be screened from the lung match following notification of the listing center, and will not receive isolated lung offers. Upon the entry or update of previously missing or expired candidate variables as described in Policy 3.7.6.3, those candidates will appear on the lung match.

Candidates awaiting a lung transplant on the Waiting List that are placed at inactive status by the listing center will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

*NOTE: Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6) (BOLDED and as of the June 24, 2005 Board of Directors Meeting) shall be approved and implemented pending distribution of appropriate notice and programming on UNet<sup>SM</sup>, if and as applicable.*

**3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age.**

Candidates listed as a Status Priority 1 or Status Priority 2 will accrue waiting time within each status priority. When waiting time is used for thoracic organ allocation, a Priority 1 and Priority 2 candidates will receive a preference over other candidates within a match run classification who have accumulated less waiting time within the same status category (see Policy 3.7.9). However, a candidate's waiting time accrued while listed as Status 2 will not be used in prioritizing the candidate for lung allocation if the candidate is upgraded to Status 1. For Priority 1 candidates, UNet<sup>SM</sup> will only consider the most recent time spent as Priority 1, i.e., UNet<sup>SM</sup> will not tally the time waiting during multiple Priority 1 periods.

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total accrued waiting time is the amount of time spent waiting as a Status 1 and Status 2.

For Priority 2 candidates, and if there is ever a tie among Priority 1 candidates, UNet<sup>SM</sup> will use total waiting time. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

*NOTE: New Policy 3.9.7.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Double lines and double strikeouts were added and approved at the June 23, 2009 Board of Directors Meeting.)*

*NOTE: New Policy 3.9.7.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Approved at the June 20, 2008 Board of Directors Meeting.)*

**3.7.10 Sequence of Adult Heart Allocation.** Donor hearts recovered from donors age 18 and older shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

Local

1. Status 1A candidates
2. Status 1B candidates

Zone A

3. Status 1A candidates
4. Status 1B candidates

Local

5. Status 2 candidate s

Zone B

6. Status 1A candidates
7. Status 1B candidates

Zone A

8. Status 2 candidates

Zone B

9. Status 2 candidates

Zone C

10. Status 1A candidates
11. Status 1B candidates
12. Status 2 candidates

Zone D

13. Status 1A candidates
14. Status 1B candidates
15. Status 2 candidates

Zone E

16. Status 1A candidates
17. Status 1B candidates
18. Status 2 candidates

**3.7.10.1 Sequence of Pediatric Heart Allocation.** Hearts recovered from pediatric donors shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

1. Combined Local and Zone A Status 1A Pediatric candidates
2. Local Status 1A Adult candidates
3. Combined Local and Zone A Status 1B Pediatric candidates
4. Local Status 1B Adult candidates
5. Zone A Status 1A Adult candidates
6. Zone A Status 1B Adult candidates
7. Local Status 2 Pediatric candidates
8. Local Status 2 Adult candidates
9. Zone B Status 1A Pediatric candidates
10. Zone B Status 1A Adult candidates
11. Zone B Status 1B Pediatric candidates
12. Zone B Status 1B Adult candidates
13. Zone A Status 2 Pediatric candidates
14. Zone A Status 2 Adult candidates
15. Zone B Status 2 Pediatric candidates
16. Zone B Status 2 Adult candidates
17. Zone C Status 1A Pediatric candidates
18. Zone C Status 1A Adult candidates
19. Zone C Status 1B Pediatric candidates
20. Zone C Status 1B Adult candidates
21. Zone C Status 2 Pediatric candidates
22. Zone C Status 2 Adult candidates
23. Zone D Status 1A Pediatric candidates
24. Zone D Status 1A Adult candidates



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

44. Zone C Status 2 ABO Secondary Candidates
45. Zone D Status 1A ABO Primary Ped Candidates for Pediatric Donor
46. Zone D Status 1A ABO Secondary Ped Candidates for Pediatric Donor
47. Zone D Status 1A ABO Primary Candidates
48. Zone D Status 1A ABO Secondary Candidates
49. Zone D Status 1B ABO Primary Ped Candidates for Pediatric Donor
50. Zone D Status 1B ABO Secondary Ped Candidates for Pediatric Donor
51. Zone D Status 1B ABO Primary Candidates
52. Zone D Status 1B ABO Secondary Candidates
53. Zone D Status 2 ABO Primary Ped Candidates for Pediatric Donor
54. Zone D Status 2 ABO Secondary Ped Candidates for Pediatric Donor
55. Zone D Status 2 ABO Primary Candidates
56. Zone D Status 2 ABO Secondary Candidates
57. Zone E Status 1A ABO Primary Ped Candidates for Pediatric Donor
58. Zone E Status 1A ABO Secondary Ped Candidates for Pediatric Donor
59. Zone E Status 1A ABO Primary Candidates
60. Zone E Status 1A ABO Secondary Candidates
61. Zone E Status 1B ABO Primary Ped Candidates for Pediatric Donor
62. Zone E Status 1B ABO Secondary Ped Candidates for Pediatric Donor
63. Zone E Status 1B ABO Primary Candidates
64. Zone E Status 1B ABO Secondary Candidates
65. Zone E Status 2 ABO Primary Ped Candidates for Pediatric Donor
66. Zone E Status 2 ABO Secondary Ped Candidates for Pediatric Donor
67. Zone E Status 2 ABO Primary Candidates
68. Zone E Status 2 ABO Secondary Candidates
69. Common OPO and Zone A Status 1A ABO Incompatible Ped Candidates for Pediatric Donor
70. Common OPO and Zone A Status 1B ABO Incompatible Ped Candidates for Pediatric Donor
71. Common OPO Status 2 ABO Incompatible Candidates
72. Zone B Status 1A ABO Incompatible Candidates
73. Zone B Status 1B ABO Incompatible Candidates
74. Zone C Status 1A ABO Incompatible Candidates
75. Zone C Status 1B ABO Incompatible Candidates
76. Zone D Status 1A ABO Incompatible Candidates
77. Zone D Status 1B ABO Incompatible Candidates
78. Zone E Status 1A ABO Incompatible Candidates
79. Zone E Status 1B ABO Incompatible Candidates
80. Common OPO and Zone A ABO Primary In Utero Candidates
81. Common OPO and Zone A ABO Secondary In Utero Candidates
82. Common OPO and Zone A ABO Incompatible In Utero Candidates
83. Zone B ABO Primary In Utero Candidates
84. Zone B ABO Secondary In Utero Candidates
85. Zone B ABO Incompatible In Utero Candidates
86. Zone C ABO Primary In Utero Candidates
87. Zone C ABO Secondary In Utero Candidates
88. Zone C ABO Incompatible In Utero Candidates
89. Zone D ABO Primary In Utero Candidates
90. Zone D ABO Secondary In Utero Candidates
91. Zone D ABO Incompatible In Utero Candidates
92. Zone E ABO Primary In Utero Candidates
93. Zone E ABO Secondary In Utero Candidates
94. Zone E ABO Incompatible In Utero Candidates

**NOTE:** *The amendments to Policy 3.7.10.1 (Sequence of Pediatric Heart Allocation) shall be effective pending notice to the membership and programming in UNet<sup>SM</sup>. (Approved at the November 17, 2009 Board of Directors Meeting.)*

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**3.7.11 Sequence of Adult Donor Lung Allocation.** Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation. If one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for adult donor lungs is as follows:

- i. 1. First locally to Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
- ii. 2. Next, locally to Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
- iii. 3. Next, locally to Local ABO identical Status Priority 1 candidates 0 – 11 years old according to length of waiting time;
- iv. 4. Next, locally to Local ABO compatible Status Priority 1 candidates 0 – 11 years old according to length of waiting time;
- v. 5. Local ABO identical Status Priority 2 candidates 0 – 11 years old according to length of waiting time;
- vi. 6. Local ABO compatible Status Priority 2 candidates 0 – 11 years old according to length of waiting time;
- vii. 7. Next, to ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
- viii. 8. Next, to ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
- ix. 9. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
- x. 10. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
- xi. 11. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
- xii. 12. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
- xiii. 13. Next, to ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
- xiv. 14. Next, to ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
- xv. 15. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
- xvi. 16. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
- xvii. 17. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
- xviii. 18. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
- xix. 19. Next, to ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;

- xx.20. ~~Next, to ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;~~
- xxi.21. ~~Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- xxii.22. ~~Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- xxiii.23. ~~ABO identical Status Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- xxiv.24. ~~ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- xxv.25. ~~Next, to ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;~~
- xxvi.26. ~~Next, to ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;~~
- xxvii.27. ~~Next, to ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- xxviii.28. ~~Next, to ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- xxix.29. ~~ABO identical Status Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- xxx.30. ~~ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- xxxi.31. ~~Next, to ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;~~
- xxxii.32. ~~Next, to ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;~~
- xxxiii.33. ~~Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time; and~~
- xxxiv.34. ~~Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time.~~
- xxxv.35. ~~ABO identical Status Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time;~~
- xxxvi.36. ~~ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time;~~

3.7.11.1 Sequence of Pediatric Donor Lung Allocation. Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D, and finally to candidates in Zone E. In each of these six geographic areas, candidates will be grouped so that candidates those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to

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applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to combined local, Zone A and Zone B candidates by status priority and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.
- Offers for 12-17 year-olds will first be made to combined local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.
- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0-11 years old is as follows:

- i. ~~First locally to ABO identical candidates 0-11 years old according to length of time waiting;~~
- ii. ~~Next, locally to ABO compatible candidates 0-11 years old according to length of time waiting;~~
1. Combined local, Zone A and Zone B ABO identical Status Priority 1 candidates 0-11 years old according to length of waiting time;
2. Combined local, Zone A and Zone B ABO compatible Status Priority 1 candidates 0-11 years old according to length of waiting time;
3. Combined local, Zone A and Zone B ABO identical Status Priority 2 candidates 0-11 years old according to length of waiting time;
4. Combined local, Zone A and Zone B ABO compatible Status Priority 2 candidates 0-11 years old according to length of waiting time;
5. Combined local and Zone A ABO identical candidates 12-17 years old according to Lung Allocation Score in descending order;
6. Combined Local and Zone A ABO compatible candidates 12-17 years old according to Lung Allocation Score in descending order;
- iii. ~~Next, locally to ABO identical candidates 12-17 years old according to Lung Allocation Score in descending order;~~
- vii. ~~Next, locally to ABO compatible candidates 12-17 years old according to Lung Allocation Score in descending order;~~
- viii. 7. Next, locally to Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
- ~~ix. 8. Next, locally to Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;~~
- vii. ~~Next, to ABO identical candidates 0-11 years old in Zone A according to length of time waiting;~~
- viii. ~~Next, to ABO compatible candidates 0-11 years old in Zone A according to length of time waiting;~~
- ix. ~~Next, to ABO identical candidates 12-17 years old in Zone A~~

- according to Lung Allocation Score in descending order;
- ~~x.~~ Next, to ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
  - ~~x.9.~~ Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
  - ~~xi.10.~~ Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
  - ~~xiii.~~ Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;
  - ~~xiv.~~ Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;
  - ~~xii.11.~~ Next, to ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
  - ~~xiii.12.~~ Next, to ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
  - ~~xiv.13.~~ Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
  - ~~xv.14.~~ Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
  - ~~xvi.15.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
  - ~~xvii.16.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
  - ~~xviii. 17.~~ ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;
  - 18. ABO compatible Status Priority 2 candidates 0-11 years old in Zone C according to length of waiting time;
  - ~~xx.19.~~ Next, to ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
  - ~~xxi.20.~~ Next, to ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
  - ~~xxii.21.~~ Next, to ABO identical candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
  - ~~xxiii.22.~~ Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
  - ~~xxiv.23.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
  - ~~xxvi.24.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
  - 25. ABO identical Status Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
  - 26. ABO compatible Status Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
  - ~~xxvii.27.~~ Next, to ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
  - ~~xxviii.28.~~ Next, to ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
  - ~~xxix.29.~~ Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
  - ~~xxx.30.~~ Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
  - ~~xxxi.31.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
  - ~~xxxii.32.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
  - 33. ABO identical Status Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
  - 34. ABO compatible Status Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;

- ~~xxxv.~~ 35. Next, to ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxvi.~~ 36. Next, to ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxvii.~~ 37. Next, to ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
- ~~xxxviii.~~ 38. Next, to ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidates age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that ~~candidates those~~ who have an ABO blood type that is identical to that of the ~~compatible (but not identical) with that of the donor~~ are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

- ~~i.~~ 1. First locally to Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
- ~~ii.~~ 2. Next, locally to Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
- ~~iii.~~ 3. Next, locally to Local ABO identical Status 1 candidates 0 – 11 years old according to length of time waiting;
- ~~iii.~~ 4. Local ABO compatible Status 1 candidates 0 – 11 years old according to length of time waiting;
- 5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of time waiting;
- 6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of time waiting;
- ~~vi.~~ 7. Next, locally to Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
- ~~vii.~~ 8. Next, locally to Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
- ~~viii.~~ 9. Next, to ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
- ~~vix.~~ 10. Next, to ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
- ~~x.~~ 11. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
- ~~xi.~~ 12. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
- ~~xii.~~ 13. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
- 14. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
- ~~xiv.~~ 15. Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
- ~~xv.~~ 16. Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

- ~~xxvi-17.~~ Next, to ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
- ~~xxvii-18.~~ Next, to ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
- ~~xxviii-19.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
- ~~xix-20.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
- 21. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
- 22. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
- ~~xxii-23.~~ Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- ~~xxiii-24.~~ Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- ~~xxiv-25.~~ Next, to ABO identical candidates 12 – 17 years old in zone C, according to Lung Allocation Score in descending order;
- ~~xxv-26.~~ Next, to ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
- ~~xxvi-27.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
- ~~xxvii-28.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
- 29. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
- 30. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
- ~~xxx-31.~~ Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
- ~~xxxi-32.~~ Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
- ~~xxxii-33.~~ Next, to ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
- ~~xxxiii-34.~~ Next, to ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
- ~~xxxiv-35.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
- ~~xxxv-36.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
- 37. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
- 38. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
- ~~xxxviii-39.~~ Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
- ~~xxxix-40.~~ Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
- ~~xxxx-41.~~ Next, to ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxxi-42.~~ Next, to ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxxii-43.~~ Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
- ~~xxxxiii-44.~~ Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
- 45. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;



46. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
- ~~xxxxvi.47.~~ Next, to ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
- ~~xxxxvii.48.~~ Next, to ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

**NOTE:** *The amendments to Policy 3.7.11 (Sequence of Adult Donor Lung Allocation) and Policy 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Double lines and double strikeouts were added and approved at the June 23, 2009 Board of Directors Meeting.)*

**NOTE:** *The amendments to Policy 3.7.11 (Sequence of Adult Donor Lung Allocation) and Policy 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation) shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>. (Approved at the June 20, 2008 Board of Directors Meeting.)*

### 3.7.12 Minimum Information for Thoracic Organ Offers.

**3.7.12.1 Essential Information.** The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

- (i) The cause of brain death;
- (ii) The details of any documented cardiac arrest or hypotensive episodes;
- (iii) Vital signs including blood pressure, heart rate and temperature;
- (iv) Cardiopulmonary, social, and drug activity histories;
- (v) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (vi) Accurate height, weight, age and sex;
- (vii) ABO type;
- (viii) Interpreted electrocardiogram and chest radiograph;
- (ix) History of treatment in hospital including vasopressors and hydration;
- (x) Arterial blood gas results and ventilator settings; and
- (xi) Echocardiogram, if the donor hospital has the facilities.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

**3.7.12.2 Desirable Information for Heart Offers.** With each heart offer, the donor center is encouraged to provide the recipient center with the following information:

- (i) Coronary angiography for male donors over the age of 40 and female donors over the age of 45;
- (ii) CVP or Swan Ganz instrumentation;
- (iii) Cardiology consult; and
- (iv) Cardiac enzymes including CPK isoenzymes.

With each heart offer, it is reasonable for the transplanting center to request a heart catheterization of the donor where the donor history reveals one or more of the following:

- (a) The donor is a male over the age of 40 or a female over the age of 45;
- (b) Segmental wall motion abnormality;
- (c) Troponin elevation;

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- (d) History of chest pain;
- (e) Abnormal EKG consistent with ischemia or myocardial infarction; or
- (f) Two or more of the following:
  - i. History of hypertension
  - ii. History of significant smoking
  - iii. Intra-cerebral bleed
  - iv. Strong family history of coronary artery disease
  - v. History of Hyperlipidemia
  - vi. History of diabetes
  - vii. History of cocaine or amphetamine use

**3.7.12.3 Essential Information for Lung Offers.** In addition to the essential information specified above for a thoracic organ offer, the Host OPO or donor center shall provide the following specific information with each lung offer:

- (i) Arterial blood gases on 5 cm/H<sub>2</sub>O/PEEP including PO<sub>2</sub>/FiO<sub>2</sub> ratio and preferably 100% FiO<sub>2</sub> within 2 hours prior to the offer;
- (ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation, and should be arranged by the Host OPO or donor center. If the Host OPO or donor center lacks the personnel and/or technical capabilities to comply, the bronchoscopy responsibility will be that of the recipient center. The inability of the Host OPO or donor center to perform a bronchoscopy must be documented. Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.1;
- (iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;
- (iv) Sputum gram stain with a description of the sputum character; and
- (v) Smoking history.

**3.7.12.4 Desirable Information for Lung Offers.** With each lung offer, the Host OPO or donor center is encouraged to provide the recipient center with the following information:

- (i) Mycology smear; and
- (ii) Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested.

**3.7.13 Status 1 Listing Verification.** A transplant center which has demonstrated noncompliance with the Status 1 criteria specified in Policy 3.7.3 (Primary Allocation Criteria) for heart candidate registration shall be audited on a random basis and any recurrence of noncompliance will result in a recommendation to the Membership and Professional Standards Committee and Executive Committee that further Status 1 heart candidate registrations from that center shall be subject to verification by OPTN contractor of the candidates' medical status prior to their Status 1 placement on the Waiting List for a period of one year.

**3.7.14 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased.** If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor,

or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

- 3.7.15 **Local Conflicts Involving Thoracic Organ Allocation.** Regarding allocation of hearts, lungs and heart-lung combinations, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Thoracic Organ Transplantation Committee and the Board of Directors.
- 3.7.16 **Allocation of Domino Donor Hearts.** A domino heart transplant occurs when the native heart of a combined heart-lung transplant recipient is procured and transplanted into a candidate who requires an isolated heart transplant. First consideration for donor hearts procured for this purpose will be given to the candidates of the participating transplant program from which the native heart was procured. If the program elects not to use the heart, then the heart will be allocated according to Policy 3.7, or an approved variance to this policy. For the purpose of Policy 3.7.16, the Local Unit of allocation for the domino heart shall be defined as the CMS-designated service area of the OPO where the domino heart is procured.
- 3.7.17 **Crossmatching for Thoracic Organs.** The transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.