第36回 厚生科学審議会疾病対策部会臓器移植委員会
議事次第

日時：平成22年9月6日(月)
16：30～18：30
場所：経済産業省別館825会議室

1. 開 会

2. 議 事
（1） 改正法の施行状況について
（2） 移植希望者(レシピエント)選択基準について
（3） 改正法の施行を踏まえた今後の検討課題について
（4） その他

3. 閉 会

〈配布資料〉
資料1－1 改正法の施行状況について
資料1－2 改正法施行後の脳死下での臓器提供事例について
資料1－3 脳死下における臓器提供事例に係る情報開示について
資料1－4 「脳死下における臓器提供事例に係る検証会議」の開催について

資料2－1 心臓移植希望者(レシピエント)選択基準(案)
資料2－2 肺移植希望者(レシピエント)選択基準(案)
資料2－3 心肺同時移植希望者(レシピエント)選択基準(案)

資料3 今後の検討課題について

資料１－１

改正法の施行状況について

１　省令・ガイドライン等の改正

・6月25日に、省令・ガイドライン等を改正。

・都道府県・政令市・中核市のほか、脳死下での臓器提供施設（いわゆる5類型に該当する施設）、関係団体等に通知を発出。

２　新たな制度についての周知・広報

（1）多様なメディアを通じた新しい制度の周知・広報

・7月13～18日：新聞各紙に政府公報を掲載（全国紙5紙、ブロック紙3紙、地方紙64紙）

・厚生労働省ホームページにトップページからアクセスできる専用ページを設置

・説明会の開催（医療機関、行政機関、マスコミを対象に、計5回開催）

・医療現場への周知のため、8つの学会に依頼し、機関誌やホームページに情報掲載

（2）改正内容を踏まえた臓器提供意思表示カード等の作成・配布

新たに作成したリーフレット一体型の臓器提供意思表示カードを7月より配布。

・新カード一体型リーフレット

400万枚作成

・免許証及び保険証用説明リーフレット

1126万枚作成

・新シール一体型リーフレット（※意思表示欄が設けられていない免許証・保険証用）

500万枚作成

・臓器提供意思登録システム

8月の新規登録者7，270人（平成21年の月平均の約3．6倍）、

22年8月末日現在の登録者数71，182人

３　施行後における脳死後の臓器提供事例への対応（資料１－２及び資料１－３参照）

7月17日以降、7例（9月4日現在）の提供があったところであり、（社）日本臓器移植ネットワークによる情報開示、記者会見等の対応を行った。

・　家族の書面による承諾により、臓器提供が行われた例（6例）

・　本人の書面による意思表示により、臓器提供が行われた例（1例）

４「脳死下における臓器提供事例に係る検証会議」の開催（資料１－４参照）

9月8日に第32回脳死下における臓器提供事例に係る検証会議を開催予定。

改正法施行後の脳死下での臓器提供事例について(平成22年9月4日現在)

脳死判定事例(提供事例)	提供日	原疾患	提供施設	書面による意思表示	心臓	肺	肝臓	膵臓	腎臓	小腸	眼球
第88例目(第87例目)	平成22年8月10日	20代♂交通外傷	関東甲信越	なし	国立循環器病研究センター	岡山大(両肺)	東大	藤田保健衛生大(膵腎同時)	群馬大	—	東京歯科大学市川総合病院 東京歯科大学市川総合病院
第89例目(第88例目)	平成22年8月19日	♂	近畿	なし	東大	阪大(両肺)	京大	名古屋第二赤十字(膵腎同時)	神戸大	—	— —
第90例目(第89例目)	平成22年8月22日	50代♀脳血管障害	東海	なし	東北大	東北大(両肺)	阪大	名古屋第二赤十字(膵腎同時)	藤田保健衛生大	—	名古屋大 藤田保健衛生大
第91例目(第90例目)	平成22年8月27日	40代♀くも膜下出血	松山赤十字病院	あり	—	—	北海道大	東京女子医大(膵腎同時)	愛媛県立中央病院	—	愛媛大 愛媛大
第92例目(第91例目)	平成22年8月29日	40代♂蘇生後脳症	関東甲信越	なし	—	京大 京大	国立成育医療研究センター 京大	九州大(膵腎同時)	千葉大	東北大	東京歯科大学市川総合病院 東京歯科大学市川総合病院
第93例目(第92例目)	平成22年9月2日	40代♀くも膜下出血	北部九州	なし	国立循環器病研究センター	東北大(両肺)	名古屋大	—	東京女子医大 長崎医療センター	東北大	— —
第94例目(第93例目)	平成22年9月4日	成人♂頭部外傷	東北	なし	東京女子医大	岡山大 京大	名古屋大	藤田保健衛生大	福島県立医大 福島県立医大	九州大	— —

資料1－2

参考資料

平成２２年９月４日
社団法人 日本臓器移植ネットワーク

厚生労働記者会 御中

[第93例目の臓器提供事例にかかる記者会見について]

情報公開の項目を満たしていないため、会見をいたします。
レシピエントの意思確認および情報公開に関する準備対応中ですので、会見までの時間は、個別の電話取材を控えていただきたくお願い申し上げます。

○ 記者レクについて

日時 ： 平成２２年 ９月 ４日（土）１０時３０分予定

場所 ： 厚生労働記者会会見室

○ 臓器提供に関する事項

臓器提供施設の都道府県と施設名：**東北地方の病院**

脳死判定終了時刻：平成２２年 ９月 ４日 ０４時００分

・本人意思不明
・提供者の年齢区分 （ １８歳以上 ）
・親族優先提供ではない

平成２２年９月４日

社団法人 日本臓器移植ネットワーク

第93例目の臓器提供事例にかかる情報公開について①

臓器提供施設名	東北地方の病院
ドナーの方の年代（10歳階級別）	成人の方
ドナーの方の性別	男性
ドナーの方の原疾患	頭部外傷
意思表示の方法	—
提供意思を表示していた臓器	—
「その他」「特記欄」への記載	—
意思表示の記載時期	—
臓器移植ネットワークの連絡受信日時	2010年　9月　3日　9時　18分
脳死判定承諾書・臓器摘出承諾書受領日時	2010年　9月　3日　15時　20分
ご家族による摘出承諾臓器	心臓、肺、肝臓、腎臓、膵臓、小腸
第１回脳死判定開始日時	2010年　9月　3日　16時 38分
第１回脳死判定終了日時	2010年　9月　3日　20時 02分
第２回脳死判定開始日時	2010年　9月　4日　02時09分
第２回脳死判定終了日時	2010年　9月　4日　04時00分

平成２２年９月４日

社団法人　日本臓器移植ネットワーク

第93例目の臓器提供事例にかかる情報公開②

＜レシピエントの第一候補者と移植実施予定施設等＞

原疾患については、最終確定するまで公表を控えてください。

移植臓器	移植実施予定施設	年代・性別	＜参考＞原疾患
心臓	東京女子医科大学病院	２０歳代・男性	拡張型心筋症
片肺	岡山大学病院	２０歳代・男性	閉塞性細気管支炎
片肺	京都大学医学部附属病院	５０歳代・男性	間質性肺炎
肝臓	名古屋大学医学部附属病院	５０歳代・女性	肝硬変
膵臓	藤田保健衛生大学病院	２０歳代・女性	１型糖尿病
腎臓	福島県立医科大学附属病院	５０歳代・男性	慢性糸球体腎炎
腎臓	福島県立医科大学附属病院	４０歳代・男性	慢性糸球体腎炎
小腸	九州大学病院	２０歳代・男性	ヒルシュスプルング病類縁疾患
心肺同時			
肝腎同時			
膵腎同時			

最終的には各摘出チームの評価を待って決定します。

今後、摘出開始時刻、移植実施施設とレシピエントの決定、搬送ルートについてFAXします。

平成２２年９月４日

社団法人 日本臓器移植ネットワーク

第93例目の臓器提供事例にかかる情報公開③

＜レシピエントの決定、摘出開始時刻＞

移植臓器	移植実施予定施設	年代・性別	原疾患
心臓	東京女子医科大学病院	２０歳代・男性	拡張型心筋症
片肺	岡山大学病院	２０歳代・男性	閉塞性細気管支炎
片肺	京都大学医学部附属病院	５０歳代・男性	間質性肺炎
肝臓	名古屋大学医学部附属病院	５０歳代・女性	肝硬変
膵臓	藤田保健衛生大学病院	２０歳代・女性	１型糖尿病
腎臓	福島県立医科大学附属病院	５０歳代・男性	慢性糸球体腎炎
腎臓	福島県立医科大学附属病院	４０歳代・男性	慢性糸球体腎炎
小腸	九州大学病院	２０歳代・男性	ヒルシュスプルング病類縁疾患
心肺同時			
肝腎同時			
膵腎同時			

摘出開始時刻	１５：５１

平成２２年９月４日
社団法人 日本臓器移植ネットワーク

第93例目の臓器提供事例にかかる情報公開④

＜搬送ルート＞

移植臓器	搬送ルート
心臓	病院 →（防災ヘリ）→ 空港 →（チャーター機）→ 羽田空港 →（緊急車両）→ 東京女子医科大学病院
片肺	病院 →（陸路）→ 空港 →（チャーター機）→ 岡山空港 →（緊急車両）→ 岡山大学病院
片肺	病院 →（陸路）→ JR 駅 →（新幹線）→ 東京駅 →（新幹線）→ 京都駅 →（救急車）→ 京都大学医学部附属病院
肝臓	病院 →（陸路）→ JR 駅 →（新幹線）→ 東京駅 →（新幹線）→ 名古屋駅 →（タクシー）→ 名古屋大学医学部附属病院
膵臓	病院 →（陸路）→ JR 駅 →（新幹線）→ 東京駅 →（新幹線）→ 名古屋駅 →（タクシー）→ 藤田保健衛生大学病院
腎臓	病院 →（陸路）→ 福島県立医科大学附属病院
腎臓	病院 →（陸路）→ 福島県立医科大学附属病院
小腸	病院 →（陸路）→ JR 駅 →（新幹線）→ 東京駅 →（タクシー）→ 羽田空港 →（定期便）→ 北九州空港 →（タクシー）→ 九州大学病院
心肺同時	
肝腎同時	
膵腎同時	

このFAXで、今回の臓器提供に関する連絡は終了いたします。
移植手術終了時間など移植に関する情報は、各移植施設にお問合せください。

平成２２年9月６日

社団法人 日本臓器移植ネットワーク

厚生労働記者会 御中

[第94例目の臓器提供事例にかかる記者会見について]

情報公開の項目を満たしていないため、会見をいたします。

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○ 記者レクについて

日時 ： 平成２２年 9月 6日（月）１３時００分予定

場所 ： 厚生労働記者会会見室

○ 臓器提供に関する事項

臓器提供施設の都道府県と施設名：関東甲信越地方の病院

脳死判定終了時刻：平成２２年 9月 6日 ０７時０７分

・本人意思不明
・提供者の年齢区分 （ １８歳以上 ）
・親族優先提供ではない

平成２２年９月６日

社団法人 日本臓器移植ネットワーク

第94例目の臓器提供事例にかかる情報公開について①

臓器提供施設名	関東甲信越地方の病院
ドナーの方の年代（10歳階級別）	成人
ドナーの方の性別	男性
ドナーの方の原疾患	蘇生後脳症
意思表示の方法	—
提供意思を表示していた臓器	—
「その他」「特記欄」への記載	—
意思表示の記載時期	—
臓器移植ネットワークの連絡受信日時	2010年　9月　2日　19時　16分
脳死判定承諾書・臓器摘出承諾書受領日時	2010年　9月　5日　15時　47分
ご家族による摘出承諾臓器	心臓、肺、肝臓、腎臓、膵臓、小腸、眼球
第１回脳死判定開始日時	2010年　9月　5日　19時　37分
第１回脳死判定終了日時	2010年　9月　5日　21時　43分
第２回脳死判定開始日時	2010年　9月　6日　05時　00分
第２回脳死判定終了日時	2010年　9月　6日　07時　07分

資料１－３

脳死下での臓器提供事例に係る情報の開示について

１．従来の対応

○ご家族の承諾を得た上で法的脳死判定（２回目）終了後に次の情報を開示

① 患者に関すること
- 性別　・10歳階級別年齢　・原疾患
- 意思表示の方法及び提供の意思表示がなされている臓器の種類
- 意思表示を書面により行った時期
- 家族署名の有無

② 提供施設に関すること
- 施設名

③ 手続き
- 移植ネットワークに提供施設より連絡が入った時刻
- ご家族より脳死判定及び臓器摘出の承諾書を得た時刻
- ご家族が摘出を承諾した臓器の種類

④ 第１回目の法的脳死判定を開始した時刻

⑤ 第１回目の法的脳死判定の終了時刻及びその結果

⑥ 第２回目の法的脳死判定を開始した時刻

⑦ 第２回目の法的脳死判定の終了時刻及びその結果

＊その後逐次、次のとおり公表。
- 移植施設が決定した時点：移植施設、移植が予定される臓器の種類、摘出手術予定開始時刻及び終了時刻等
- 摘出手術が開始された時点：開始時刻、終了予定時刻、搬送経路（予定）
- 摘出手術が終了した時点：終了時刻、摘出臓器の種類、搬送経路

２．今回の法改正を踏まえた対応

○法改正及びそれに伴うガイドライン等の改正を踏まえ、次のとおりとしている。

① 第一報時に次の情報を付記する。
- 本人意思　（表示あり・不明）
- 提供者の年齢区分　（　　）
  括弧内は下記のいずれか
  6 歳未満、6 歳以上 10 歳未満、10 歳以上 15 歳未満、（10 歳代前半でも可）
  15 歳以上 18 歳未満、18 歳以上
- 親族優先提供　（である・ではない）

② 親族優先提供に該当の場合は、公表資料に次の項目を追加する。
- 親族に移植される臓器：親族関係
- 親族関係を確認した書類
- 親族移植施設、年代･性別、原疾患

○参考資料
・臓器移植法に基づく脳死下での臓器移植事例に係る検証に関する最終報告書（平成 11 年 10 月 27 日：公衆衛生審議会疾病対策部会臓器移植専門委員会）

参考資料

平成11年10月27日
公衆衛生審議会疾病対策部会臓器移植専門委員会

臓器移植法に基づく脳死下での臓器移植例に係る検証に関する最終報告書（抄）

1　臓器移植の透明性確保と臓器提供者等のプライバシー保護の両立について

＜1　これまでの経緯＞

1　本年2月に臓器移植法施行後初の脳死下での臓器提供が行われて以降、臓器移植の透明性の確保と臓器提供者等のプライバシーの保護の両立を図ることが極めて重要な課題となってきている。

2　厚生省は、これまで、臓器提供事例において、移植医療の透明性の確保の観点から、臓器提供者の御家族に対して事実関係及び医学情報が開示されることを十分に納得していただくよう努力し、これまでの事例に基づき、基本的に開示されるべき項目を定め、御家族に示している。

3　それらの状況を踏まえた上で、厚生省から、平成11年8月12日の本委員会において、そのような努力をしてもなお、情報公開について御家族の承諾がどうしても得られない場合についての対応方針が示された。また、同省から、平成11年9月14日の本委員会において、8月12日に示された方針は、臓器提供者の御家族に対して事実関係及び医学情報が開示されることを十分に納得していただくよう努力してもなお、情報開示について御家族の承諾がどうしても得られない場合には、情報開示について臓器提供者及び御家族のプライバシーの保護を原則とするという基本的なスタンスを提示したものであるとの説明があった。

＜2　今後の方針について＞

1　脳死下での臓器提供事例における情報開示については、中間報告において示された7つの観点：
（1）第三者による監視・検証システムの必要性（密室性の打破）
（2）移植医療に関する国民への啓発普及の一環としての情報開示の必要性
（3）臓器提供における任意性の確保
（4）個人の医療情報に係る保護
（5）ドナーとレシピエントの遮断（匿名性の確保）
（6）礼意の保持
（7）臓器提供者とその御家族の保護

に沿った形で行われるべきであって、臓器提供者及び御家族のプライバシーが侵害されない範囲において透明性の確保が図られることが重要であると考える。

2　また、本委員会として、これまで厚生省において基本的に開示されるべき項目を定めて御家族に示すことにより情報開示について十分に納得していただくよう努力してきたことを評価する。

3　なお、脳死下での臓器提供が行われたという情報、及びそれに伴い移植が行われたという情報のみについては、臓器提供者が特定されるおそれがあるとは考えられず、臓器提供者又は御家族のプライバシーを侵害するものではないので、御家族の開示に係る承諾が得られない場合においても開示されるべきであると考える。ただし、その他の具体的開示項目については、原則的に御家族の承諾に基づき、個別事例に即した判断により決定すべきであると考える。

4　また、本委員会として、厚生省においても、移植医療の透明性の確保の重要性についても十分に認識し、御家族の承諾を得ない非開示情報開示を行うことが可能な場合があるかどうか、または御家族に情報開示の重要性についてより深く御理解いただくためにどうような方策があるかどうか等の点について、今後起きる個別事例に即して検討していく方向であることを確認した。

資料１－４

「脳死下における臓器提供事例に係る検証会議」の開催について

１　検証会議の現状

○　平成 11 年 10 月の公衆衛生審議会臓器移植専門委員会報告に基づき、設けられた。移植医療が国民の間に広く定着するまでの間、第三者の立場で検証を行うことが目的。

○　平成 12 年３月より平成 21 年３月までの間に、合計３１回開催。

○　改正法の施行時点（本年７月）における脳死判定事例 86 例のうち、55 例目まで検証を実施。今後、56 例目（平成 19 年 5 月提供分）以降の検証を進める。

２　当面の開催方針（案）

○　当面は、現行の方法で医学的検証作業グループ及び検証会議本体を可能な限り開催し、56 例目以降の事例の検証を進める。

※　過去最も速いペースでは、検証会議を３か月に１回程度開催し、１回の会議で４事例程度を検証している。

※　このペースでも、年間 16 例程度。

※　先述のとおり、改正法施行前の未検証事例は 32 例。

○　改正法施行により新たに可能となった家族承諾により脳死下臓器提供を行った事例（９月４日までで６例）については、上記の未検証事例すべての検証を待たず、これらと並行する形で早めに検証を行う。

※　例えば、提供後のドナー家族のケアの状況等を含め、１年程度経過した時点で検証するとした場合、来年夏頃の検証会議となる。

３　今後の課題等

（１）課題

○ 改正法により新たに可能となった事例への対応

・15 歳未満の小児からの提供事例

・本人の意思表示が不明であり、家族承諾により提供を行った事例

○ 改正法施行により、臓器提供数の増加が見込まれることへの対応

○ 改正法施行前の未検証事例（32 例）への対応

（２）検討の進め方

現行方式での検証作業を進めつつ、今後の迅速かつ効率的・効果的な検証方法について、検証会議の先生方の御意見も伺い、具体的な方策を検討する。

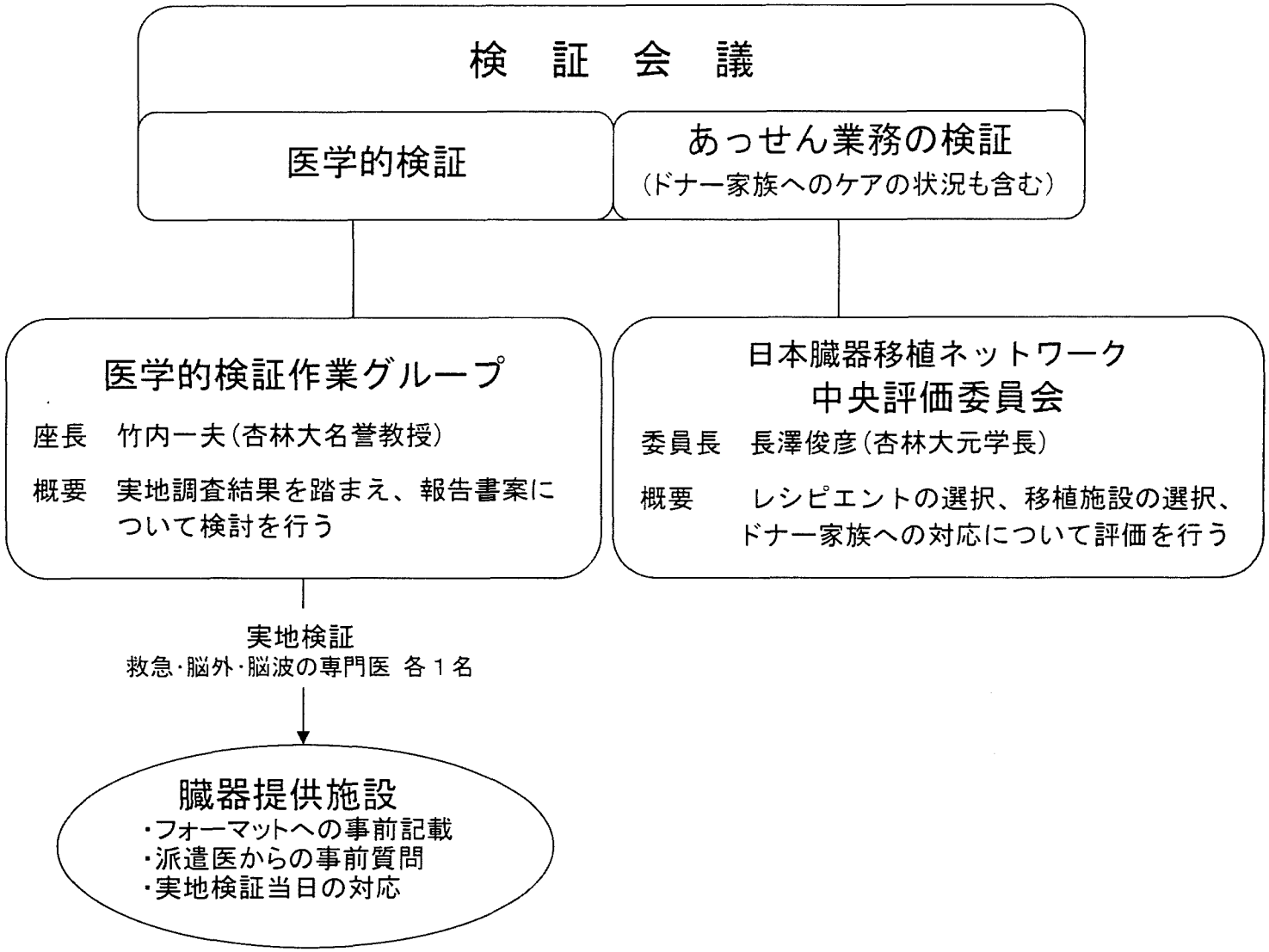
脳死下での臓器提供者数及び検証実施件数の推移（年度別）

年度	臓器提供者数	検証実施件数	検証会議開催数
平成9年度	0	0	0
平成10年度	1	0	0
平成11年度	4	4	0
平成12年度	8	4	5
平成13年度	5	5	6
平成14年度	5	6	5
平成15年度	5	4	2
平成16年度	8	3	2
平成17年度	8	7	3
平成18年度	9	6	3
平成19年度	13	9	3
平成20年度	15	7	2
平成21年度	5	0	0
平成22年度	7	0	0
合計	93	55	31

○脳死下での臓器提供者数は、法施行以降平成22年7月16日（改正法施行前）までに累計86例（脳死判定件数は87例）

○これらはすべて15歳以上の方の提供事例であり、改正法の施行に伴う15歳未満の方の提供事例はまだ発生していない。（平成22年9月6日現在）

（参考）　現行の検証作業


検　証　会　議
医学的検証
あっせん業務の検証
（ドナー家族へのケアの状況も含む）
医学的検証作業グループ
座長　竹内一夫（杏林大名誉教授）
概要　実地調査結果を踏まえ、報告書案について検討を行う
日本臓器移植ネットワーク
中央評価委員会
委員長　長澤俊彦（杏林大元学長）
概要　レシピエントの選択、移植施設の選択、ドナー家族への対応について評価を行う
実地検証
救急・脳外・脳波の専門医　各１名
臓器提供施設
・フォーマットへの事前記載
・派遣医からの事前質問
・実地検証当日の対応

資料2－1

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が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：　Status１：次の（ア）から（エ）までのいずれか１つ以上に該当する状態。

（ア）補助人工心臓を装着中の状態

（イ）大動脈内バルーンパンピング（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、18 歳未満に限り、重症室に収容されていない場合であって、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（重症室に収容されていない場合であって、登録中に 18 歳以上となった場合には Status２とする）

Status２：待機中の患者で、上記以外の状態

Status３：Status１、Status２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

Status１、Status２の順に優先する。（３．の具体的選択方法を参照）。また、Status３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、Status１又は Status２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、日本臓器移植ネットワークに移植希望者（レシピエント）の登録を行った時点において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。

○Status１の移植希望者（レシピエント）間では、待機期間はStatus１の延べ日数とする。

（注）移植希望者（レシピエント）の登録時に１８歳未満で、Status１（エ）に該当していた患者が、その後１８歳以上となり、重症室に収容されていないためStatus２となったが、再度、Status１の状態となったときは、１８歳未満にStatus１に該当していた期間もStatus１の延べ日数に含まれる。

○Status２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	１８歳未満	一致
2			適合
3		１８歳以上	一致
4			適合
5	Status 2	１８歳未満	一致
6			適合
7		１８歳以上	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。

4．その他

将来、Status１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、Status２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。このことを含め、今後、新たな医学的知見などを踏まえ、緊急度の定義やブロック制の導入などについて、適宜選択基準の見直しをすることとする。

参考資料1

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

1A 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

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 >/= 7.5 mcg/kg/min, or milrinone >/= .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[SM] 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^{SM} 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^{SM} 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 18th 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 > / = 7.5 mcg/kg/min or milrinone > / =.50 mcg/kg/min) or multiple inotropes (*e.g.*, addition of dopamine at > / = 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^{SM} 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^{SM} 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 < / =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.*, + 5th 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 < 5th 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^{SM} 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 $D^{\ddagger}$ – see 3.7.6.1.a)
3.	O_2 required at rest (Groups A, C, and $D^{\ddagger}$ – 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_2 (see 3.7.6.1.b)
12.	Bilirubin (current bilirubin – all gGroups; change in bilirubin – Group B; see 3.7.6.1.c)

Table 2
Factors that Predict Survival after Lung Transplant

1.	FVC (Groups B and D– see 3.7.6.1.a)
2.	PCW pressure ≥ 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
e. **Lung Allocation Score**	**74.3**	**78.0**

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 ≤ 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_2 in the Lung Allocation Score

UNet[SM] will use two measures of PCO_2 in a candidate's lung allocation score calculation: current PCO_2, and change in PCO_2. There are two types of PCO_2 change calculations: "threshold change" and "threshold change maintenance." The following explanations (i-vi) and illustrations (Figures 1-3) detail how UNet[SM] uses PCO_2 in the lung allocation score.

(i) *Use of Arterial, Venous, or Capillary PCO_2 Values*
In UNet[SM], a center may enter a PCO_2 value from an arterial, venous, or capillary blood gas test. UNet[SM] will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNet[SM] will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNet[SM] will use the PCO_2 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[SM] will use the arterial value in the lung allocation score calculation.

(ii) *Definition of Current PCO_2*
Current PCO_2 is the PCO_2 value with the most recent test date entered in UNet[SM].

(iii) *Expiration of Current PCO_2 Value*
UNet[SM] will evaluate a current PCO_2 value as expired according to Policy 3.7.6.3.2.

(iv) *Use of Normal Clinical Value for Current PCO_2*
The normal clinical value of PCO_2 is 40 mmHg. UNet[SM] will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO_2 is less than 40 mmHg, missing, or expired.

(v) *PCO_2 Values Used in the Change Calculations*
There are two types of PCO_2 change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO_2 change is 15% or higher. In this calculation, UNet[SM] will use highest and lowest values of PCO_2. 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[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet[SM] will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is **[(highest PCO_2 – lowest PCO_2)/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_2 value must be at least 15% higher than the lowest value used in the threshold change

calculation. The equation for threshold change maintenance is **[(current PCO_2 – lowest PCO_2)/lowest PCO_2]**.

UNet[SM] will perform the threshold change maintenance calculation either when the current PCO_2 value expires (Policy 3.7.6.3.2) or a new current PCO_2 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_2 value can be the highest one that was used in the threshold change calculation. If a current PCO_2 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_2 value expires, UNet[SM] 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_2 value for a candidate who has lost the impact from threshold change, UNet[SM] will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the threshold change calculation, UNet[SM] will *reapply* the impact from threshold change to the candidate's lung allocation score.

(vi) *Impact of PCO_2 Threshold Change in the Lung Allocation Score*
A change in PCO_2 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_2 is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO_2 in the Lung Allocation Score

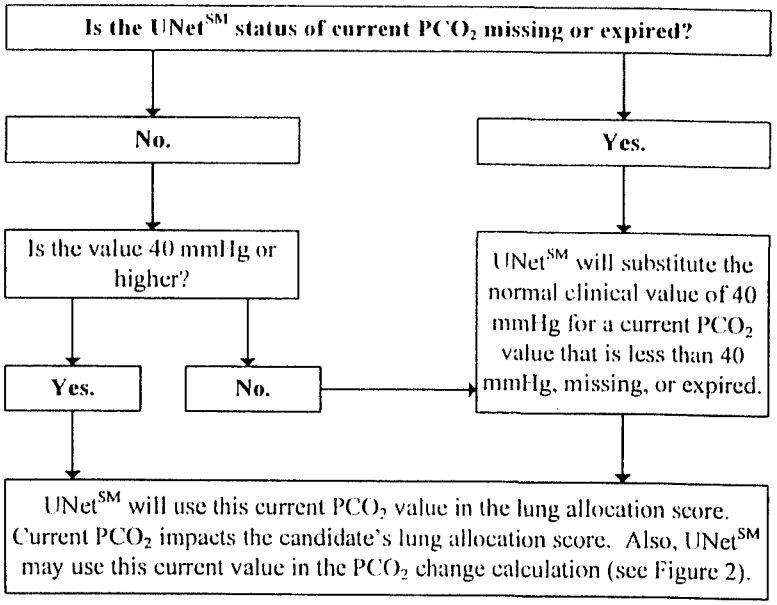


Figure 2
PCO_2 Threshold Change Calculation

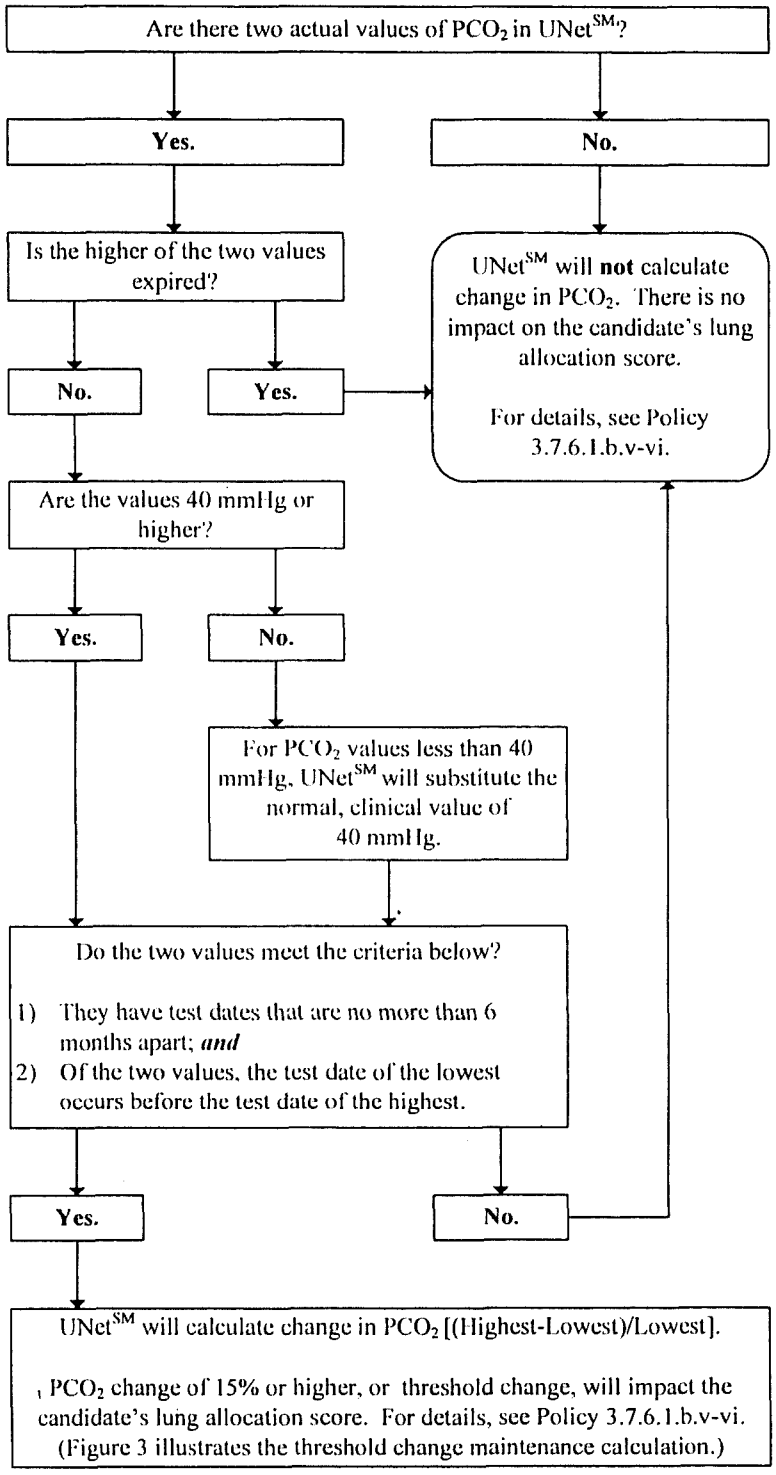
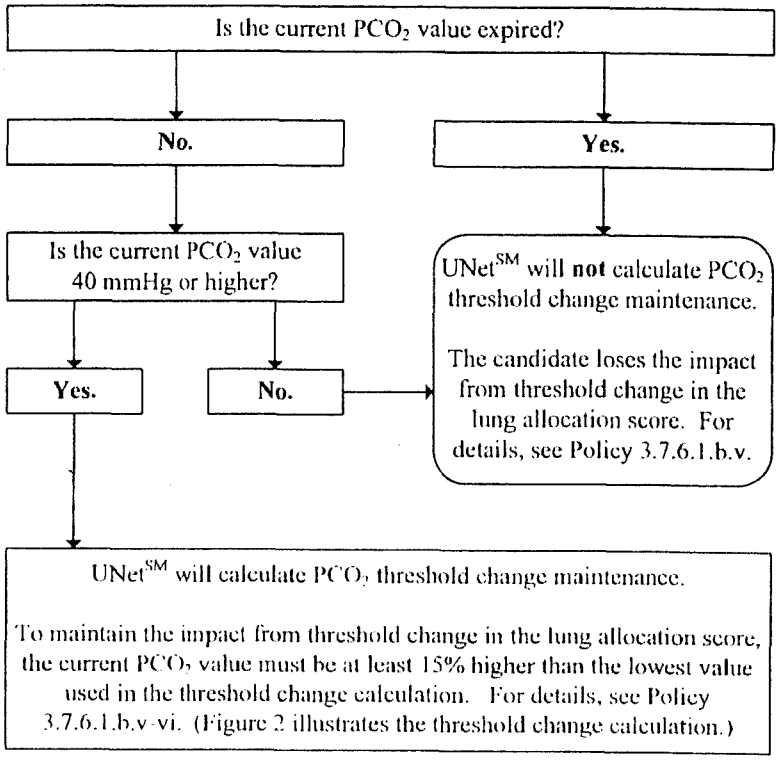


Figure 3
PCO_2 Threshold Change Maintenance Calculation



c. *Bilirubin in the Lung Allocation Score*

UNet[SM] 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[SM] 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[SM]. UNet[SM] 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[SM] 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[SM] 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[SM] 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[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet[SM] 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[SM] 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[SM] 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[SM] 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[SM] 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[SM] ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each ~~status~~ priority, UNet[SM] will rank

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[SM] will only consider the most current period of time a candidate has spent as Priority 1, i.e, UNet[SM] 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[SM] 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[SM]. 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[SM] registration, then the candidate's ~~status~~ Priority 1will ~~automatically~~ revert to ~~Status~~ Priority 2. UNet[SM] 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[SM] on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet[SM] will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet[SM] 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^2, ~~recurrent~~ syncope, or hemoptysis

  Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet[SM]. 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:**
  - 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℠. (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℠. (Approved at the June 20, 2008 Board of Directors Meeting.)

3.7.6.3 **Candidate Variables in UNet℠.** Entry into UNet℠ 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℠ 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

b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNet[SM].

(iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:

a. Is ~~L~~listed prior to age 2;
b. Is ~~L~~listed at Status 1A or 1B;
c. Has ~~C~~current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNet[SM]; 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 < 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 >6 months old > 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 recipientscandidates >6 months old >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[SM]. 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[SM]. (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[SM]. (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[SM] 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[SM] 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[SM] (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[SM] on June 1, 2005, and the approval for Candidate Y's score was entered in UNet[SM] 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^{SM} 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^{SM}, 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^{SM} will only consider the most recent time spent as Priority 1, i.e., UNet^{SM} 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, those 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^{SM} 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^{SM}. (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^{SM}. (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[SM]. (Approved at the November 17, 2009 Board of Directors Meeting.)***

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 those six geographic areas, c~~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

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~~ priorityand 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 old 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 candidate-s 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 1candidates 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 1candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xi.~~12. ~~Next, to~~ ABO compatible ~~Status~~ Priority 1candidates 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;

~~xvi.~~17. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

~~xvii.~~18. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

~~xviii.~~19. ~~Next, to~~ ABO identical ~~Status~~ Priority 1candidates 0 – 11 years old in Zone B according to length of time waiting;

~~xix.~~20. ~~Next, to~~ ABO compatible ~~Status~~ Priority 1candidates 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 1candidates 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[SM]. (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[SM]. (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;

(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_2$0/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2 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.

参考資料2

EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS BOARD OF DIRECTORS MEETING

June 19-20, 2008

Richmond, Virginia

Dr. Pruett called the meeting to order at 3:00 p.m. on June 19, 2008. A quorum was present, and 33 of the Board members were in attendance during the meeting.

The Board appointed Dolph Chianchiano, J.D. to fill the vacancy created by the passing of Flora Solarz, M.P.S., ATR, representing the General Public category on the Board of Directors.

The Board approved several resolutions contained in the Consent Agenda in a single vote. The subject of the various individual resolutions follows here:

1. The Board approved modifications to the Bylaws Appendix B, Attachment I, Section XIII (Transplant Programs), D (2) and (4) (Designated Transplant Program Criteria), to require written notification (or disclosures) to living kidney and liver donors from recipient transplant programs.

2. The Board approved the minutes of the February 20-21, 2008, Meeting of the Board of Directors in Orlando, Florida.

3. The Board approved modifications to Policy 3.6.4.1 (Adult Candidate Status) to clarify that CVVHD (continuous veno-venous hemofiltration) is a "form of dialysis" for the purpose of calculating MELD score.

4. The Board approved modifications to the Bylaws, Appendix B, Attachment I, Section XIII, D, (4) (Liver Transplant Programs that Perform Living Donor Liver Transplants) to clarify that a center is expected to inactivate or stop performing living donor transplants if the applicable Bylaw requirements are not met by the end of the conditional approval period.

5. The Board approved modifications to Policy 5.5 (Standard Organ Packaging Specifications) to define "a plastic bag" as "a red plastic biohazard bag" and to promote consistency within the policies.

Following passage of the Consent Agenda, the Board approved the OPTN 2009 Operating Budget and an increase in the Registration Fee to $547 based upon the projected level of operational activities.

The Board approved the 2007 audited financial statements for OPTN Operations and the related OMB Circular A-133 compliance audit for the year ended September 30, 2007.

The Board approved modifications to Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatch Kidneys) that will eliminate mandatory sharing of kidneys at the regional and national levels for adult candidates who have a sensitization level (PRA or CPRA) less than 20%.

The Board approved modifications to Policies 3.5.3.5 (Time Limit); 3.8.1.7.1 (Organ Offer Limit); and 7.6.1.2 (Validation of Offers) to clarify the time limits for offering zero antigen mismatched kidneys, with additional amendments to specify that the Host OPO must, rather than may, either allocate the organ according to the standard geographic sequence of kidney and pancreas allocation or allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

The Board approved modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients) to allow the Organ Center to reinstate a pancreas recipient's waiting time after the recipient's graft had failed but before a pancreatectomy was performed.

The Board of Directors approved modifications to the Bylaws Appendix A, Sections 3.01A and 5.05A, and new Section 5.07A, regarding restoration of full membership privileges following an adverse action, with additional amendments to Section 5.07A to clarify the section further. The purpose of the proposal is two-fold: to better define how a Member may be considered for restoration of full membership privileges, and to clarify the way to move from "Member Not in Good Standing" to a lesser action, such as Probation.

The Board approved modifications to Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age), which will extend offers nationally to all 0-11 year old Status 1A pediatric liver and combined liver-intestine candidates before making local adult Status 1A offers for the 0-10 donor age group in order to reduce pediatric waiting list mortality.

The Board approved modifications to Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation), and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation), which will allow the creation of a stratified allocation system for 0-11year-old lung candidates to improve access to organs for the sickest candidates by more broadly sharing young pediatric donor lungs to reduce pediatric waiting list mortality.

The Board approved modifications to Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation), which incorporate all pediatric donor hearts into the current adolescent algorithm and share these hearts more broadly to the sickest candidates to reduce pediatric waiting list mortality.

The Board tabled a proposed statement acknowledging that living-related organ donation from persons currently incarcerated is ethical and should be permissible under certain circumstances pending review by the Living Donor Committee.

The Board approved non-substantive modifications to the OPTN Charter to remove language that unnecessarily referenced expired OPTN contracts.

The Board ratified Executive Committee-approved modifications to Policies 4.6 (Screening Potential Organ Donors for Transmission of Diseases or Medical Conditions, Including Malignancies) and 2.2 (Evaluation of Potential Donors) to specify that donors may be tested for transmissible diseases using FDA-licensed, approved, or cleared serological tests capable of determining whether the donor is or has been infected with these specific diseases.

The Board ratified Executive Committee-approved modifications to Policy 3.2.1.2 (Prohibition of Access by Non Members) to clarify appropriate access to UNet^{sm}, including the requirement to have a data use agreement with third parties to whom the member has granted access to UNet^{sm}.

The Board resolved to support efforts by the Association of Organ Procurement Organizations (AOPO) to encourage the Centers for Disease Control and Prevention (CDC) to develop an updated and comprehensive definition of "high risk donor" for organs recovered for transplantation.

The Board approved modifications the Bylaws Article I (Members), Article II (Board of Directors), and Article VI (Officers) that would permit each Histocompatibility Laboratory and Medical/Scientific Member to receive one vote in the OPTN/UNOS matters and remove the need for separate national elections for both the Histocompatibility Member and Medical/Scientific Member electors. The MPSC will consider whether to retain the elector system that remains for Public Organization Members and Individual Members.

The Board approved a pilot program for a national Kidney Paired Donation System (KPD).

The Board approved modifications to Policies 3.11.4 (Combined Intestine-Liver Candidates); 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates); and 3.6.4.8 (Combined Liver-Intestine Allocation) to eliminate potential confusion about which match run to use for the allocation of combined liver-intestine grafts.

The Board referred a proposed Statement on Organ Trafficking back to the Ethics Committee for further review in light of the recent Istanbul conference on organ transplantation.

参考資料3

HEART TRANSPLANTATION

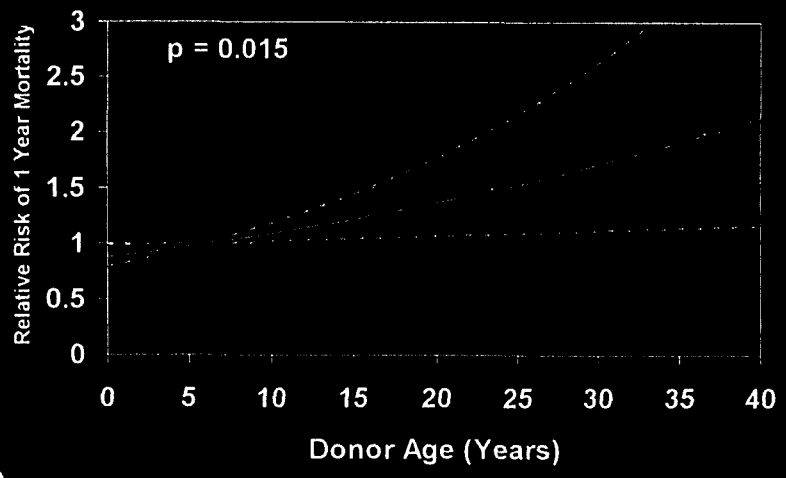
Pediatric Recipients

ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049

PEDIATRIC HEART TRANSPLANTS (1/1995-6/2007)

Risk Factors for 1 Year Mortality
Donor Age



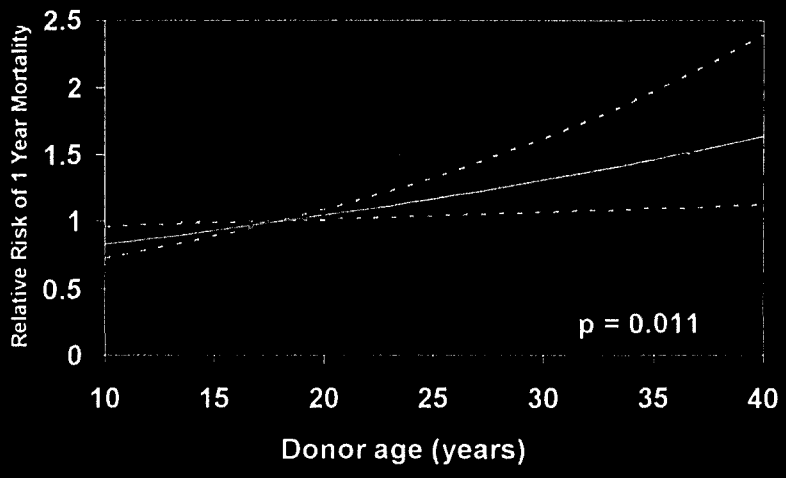
ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049

N=3,756

PEDIATRIC HEART TRANSPLANTS (1/1995-6/2007)

Risk Factors for 1 Year Mortality in Age = 11-17 Years
Donor Age



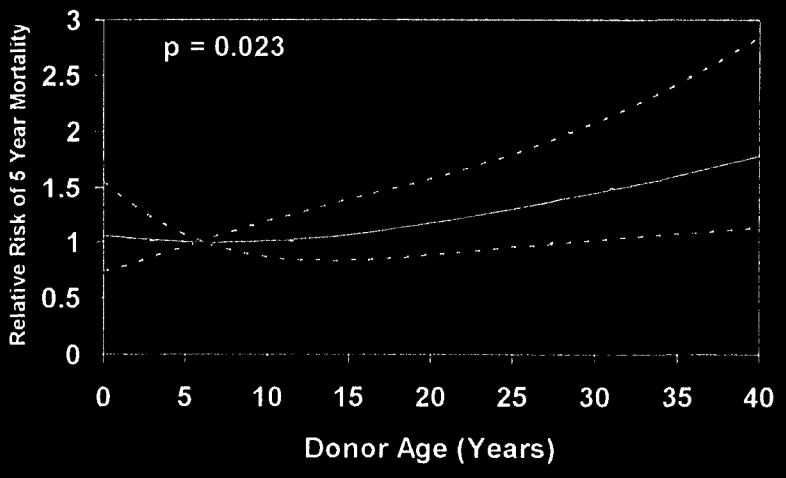
ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049

N=1,330

PEDIATRIC HEART TRANSPLANTS (1/1995-6/2003)

Risk Factors for 5 Year Mortality
Donor Age



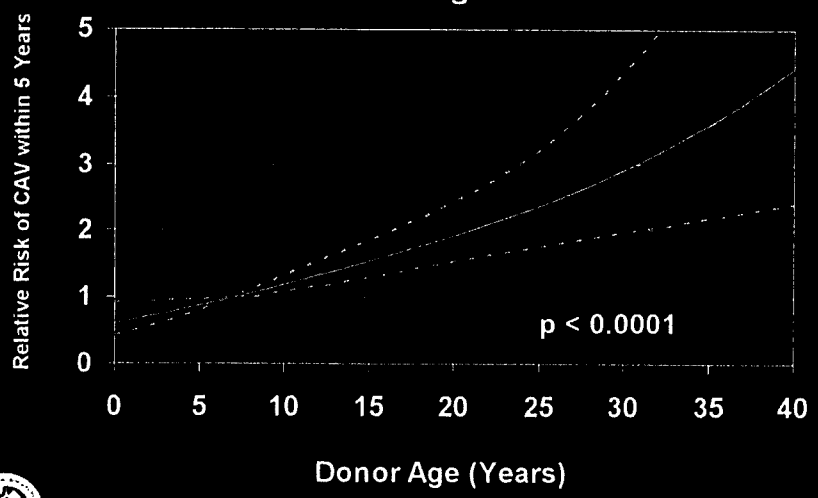
ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049

N=2,364

PEDIATRIC HEART TRANSPLANTS (7/1996-6/2003)

Risk Factors for the Development of CAV within 5 Years
Donor Age



ISHLT 2009 N=697

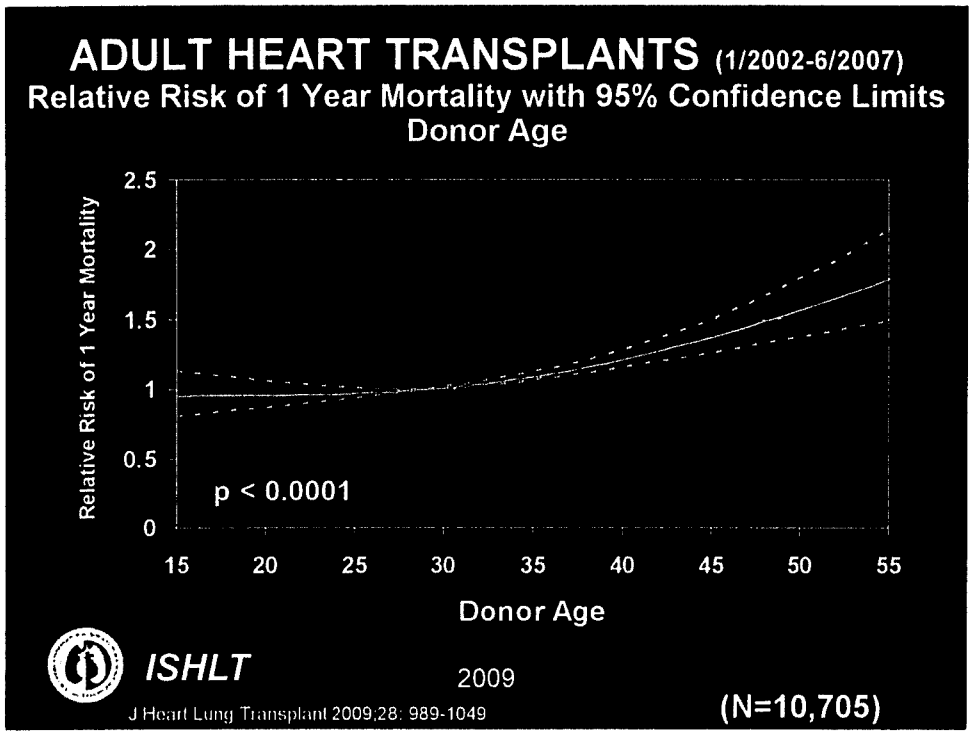
J Heart Lung Transplant 2009;28: 989-1049

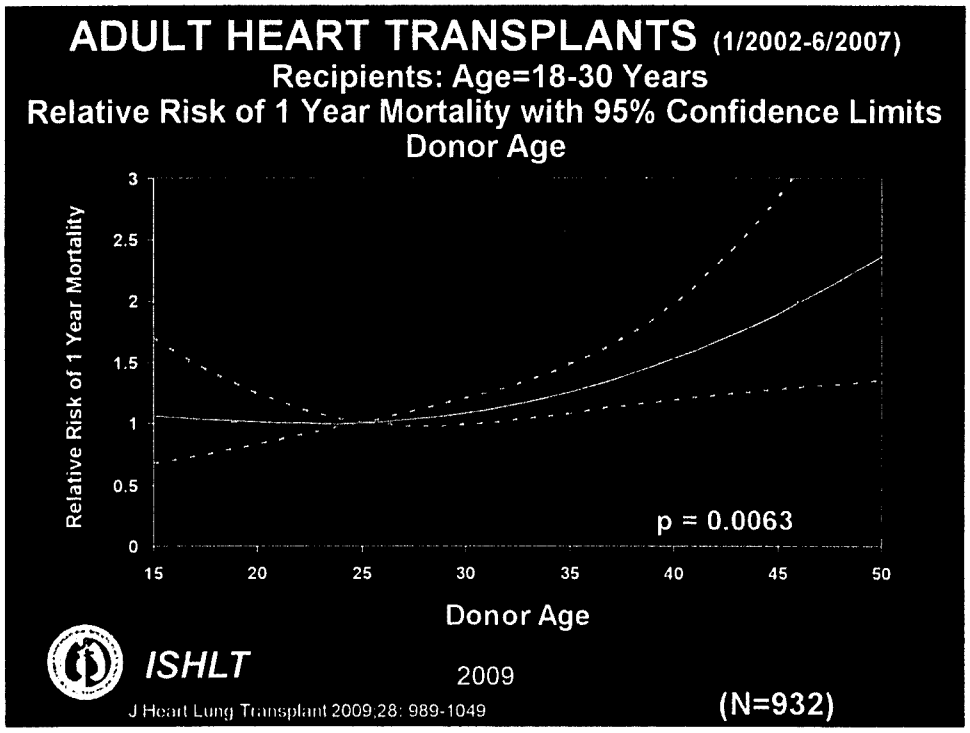
HEART TRANSPLANTATION

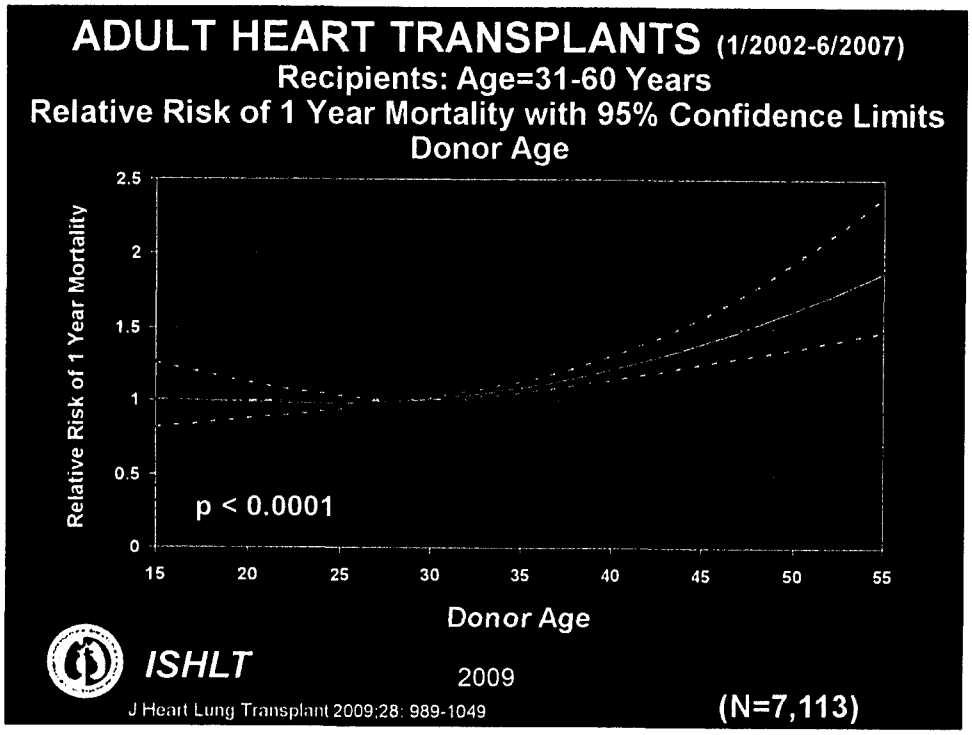
Adult Recipients

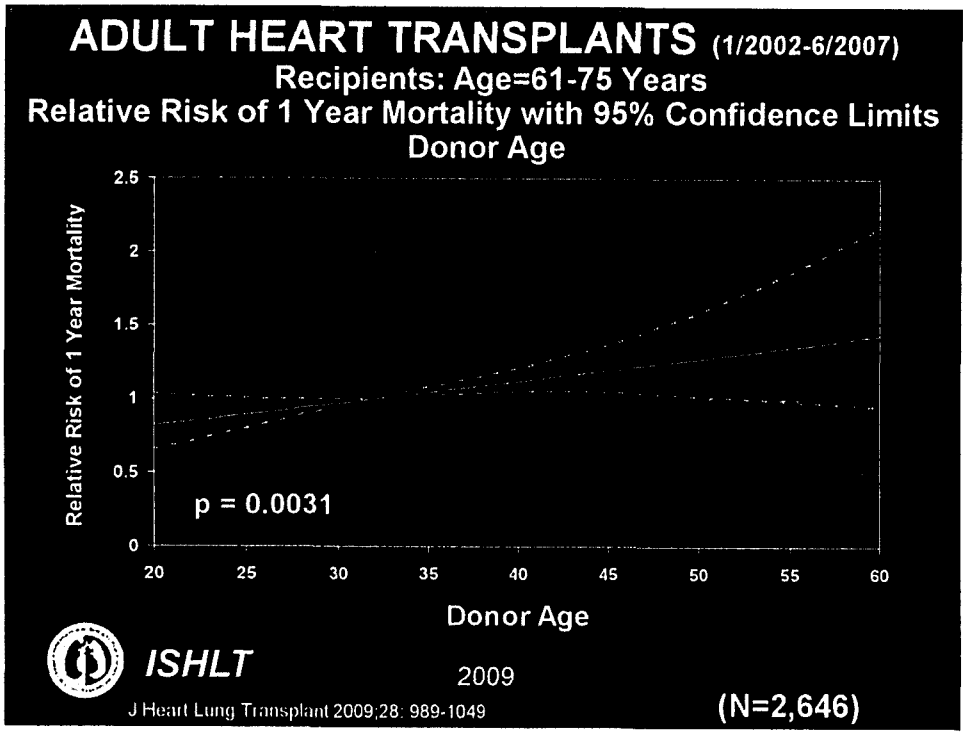
ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049


ADULT HEART TRANSPLANTS (1/2002-6/2007)
Relative Risk of 1 Year Mortality with 95% Confidence Limits
Donor Age
Relative Risk of 1 Year Mortality
2.5
2
1.5
1
0.5
0
p < 0.0001
15
20
25
30
35
40
45
50
55
Donor Age
ISHLT
2009
J Heart Lung Transplant 2009;28: 989-1049
(N=10,705)

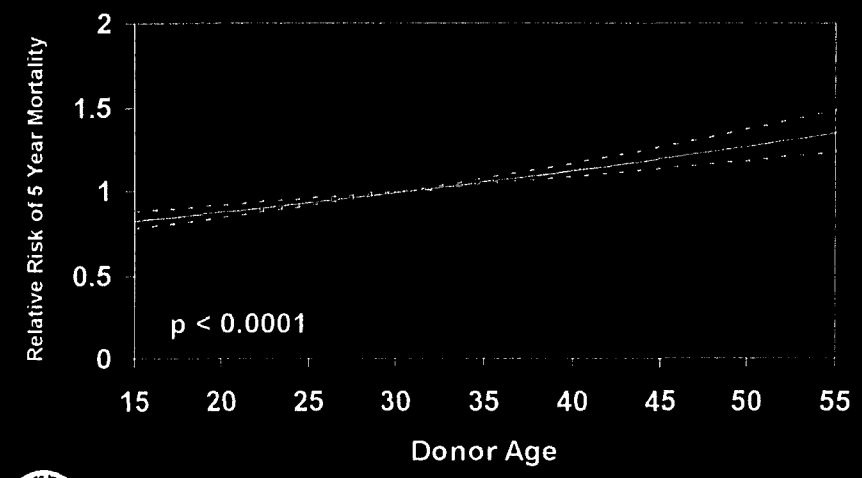

ADULT HEART TRANSPLANTS (1/2002-6/2007)
Recipients: Age=18-30 Years
Relative Risk of 1 Year Mortality with 95% Confidence Limits
Donor Age
Relative Risk of 1 Year Mortality
3
2.5
2
1.5
1
0.5
0
p = 0.0063
15
20
25
30
35
40
45
50
Donor Age
ISHLT
2009
J Heart Lung Transplant 2009;28: 989-1049
(N=932)


ADULT HEART TRANSPLANTS (1/2002-6/2007)
Recipients: Age=31-60 Years
Relative Risk of 1 Year Mortality with 95% Confidence Limits
Donor Age
Relative Risk of 1 Year Mortality
2.5
2
1.5
1
0.5
0
p < 0.0001
15
20
25
30
35
40
45
50
55
Donor Age
ISHLT
2009
J Heart Lung Transplant 2009;28: 989-1049
(N=7,113)


ADULT HEART TRANSPLANTS (1/2002-6/2007)
Recipients: Age=61-75 Years
Relative Risk of 1 Year Mortality with 95% Confidence Limits
Donor Age
Relative Risk of 1 Year Mortality
2.5
2
1.5
1
0.5
0
p = 0.0031
20
25
30
35
40
45
50
55
60
Donor Age
ISHLT
2009
J Heart Lung Transplant 2009;28: 989-1049
(N=2,646)

ADULT HEART TRANSPLANTS (1/2000-6/2003)

Relative Risk of 5 Year Mortality with 95% Confidence Limits
Donor Age



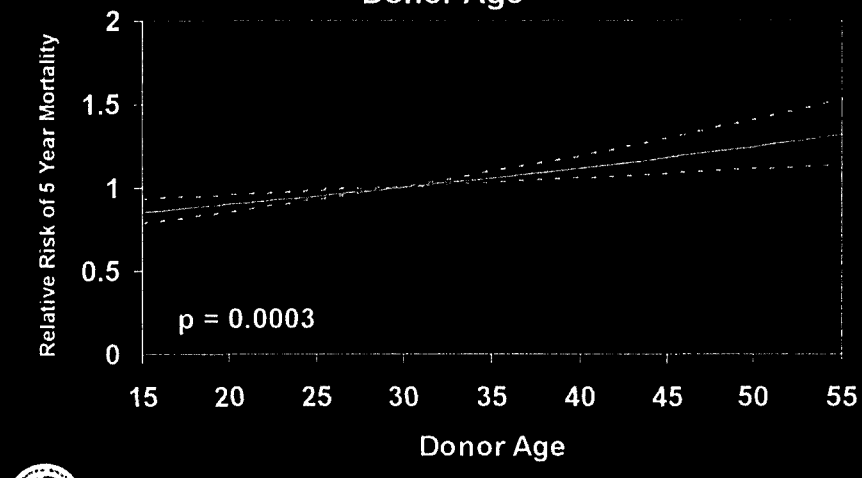
ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049

(N=7,171)

ADULT HEART TRANSPLANTS (1/2000-6/2003)

Relative Risk of 5 Year Mortality with 95% Confidence Limits
Conditional on Survival to 1 Year
Donor Age



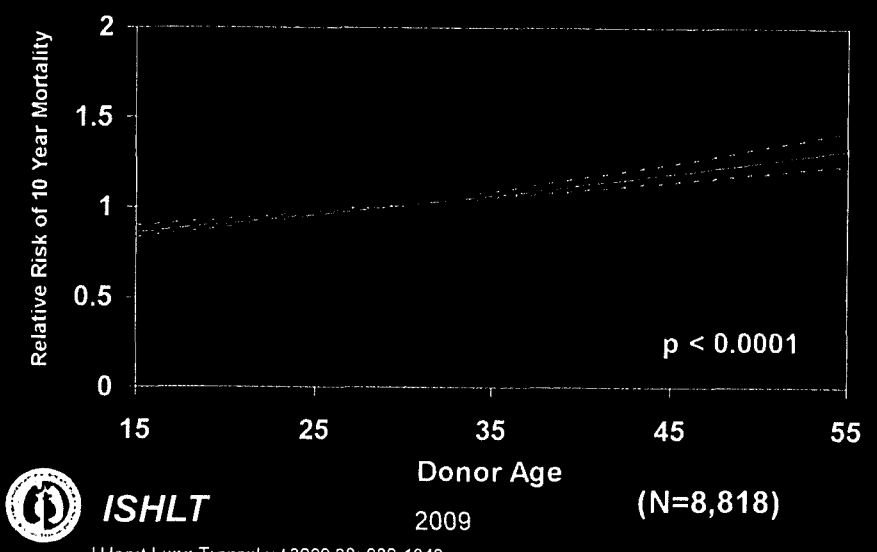
ISHLT 2009

J Heart Lung Transplant 2009;28: 989-1049

(N=5,857)

ADULT HEART TRANSPLANTS (7/1994-6/1998)

Relative Risk of 10 Year Mortality with 95% Confidence Limits
Donor Age



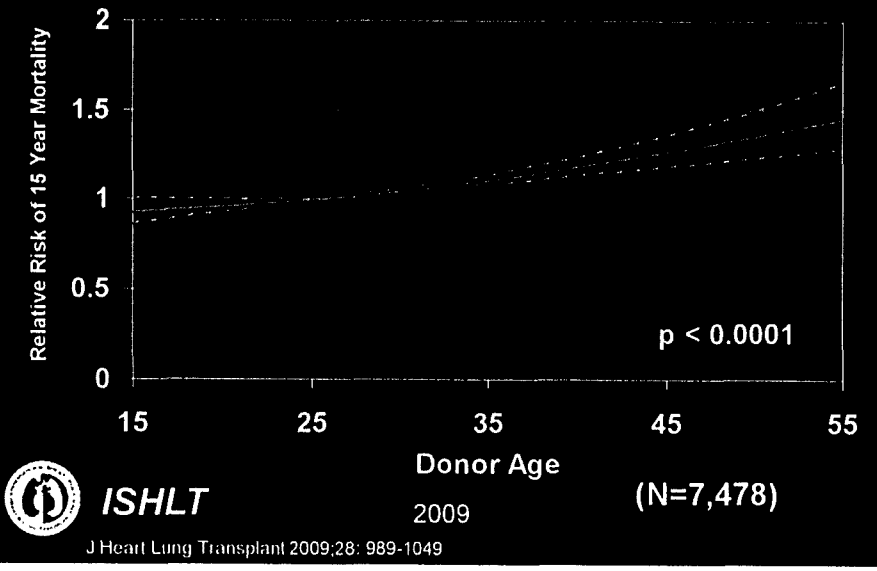
ISHLT 2009

(N=8,818)

J Heart Lung Transplant 2009;28: 989-1049

ADULT HEART TRANSPLANTS (1989-6/1993)

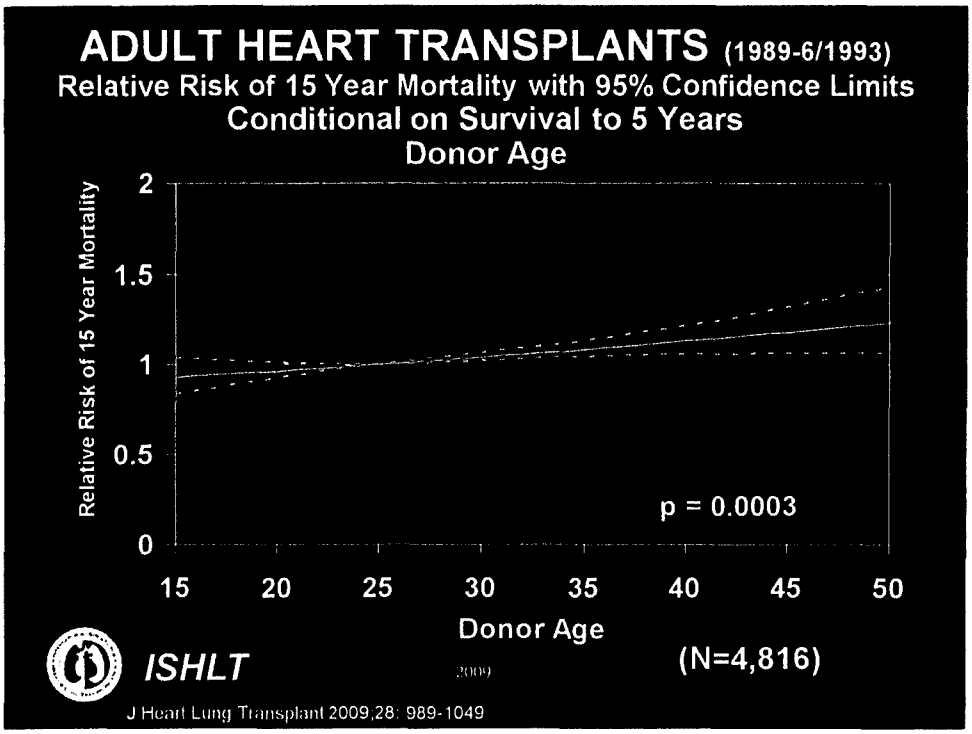
Relative Risk of 15 Year Mortality with 95% Confidence Limits
Donor Age



ISHLT 2009

(N=7,478)

J Heart Lung Transplant 2009;28: 989-1049


ADULT HEART TRANSPLANTS (1989-6/1993)
Relative Risk of 15 Year Mortality with 95% Confidence Limits
Conditional on Survival to 5 Years
Donor Age
Relative Risk of 15 Year Mortality
2
1.5
1
0.5
0
p = 0.0003
15
20
25
30
35
40
45
50
Donor Age
ISHLT
2009
(N=4,816)
J Heart Lung Transplant 2009;28: 989-1049

資料2－2

肺移植希望者（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）肺の大きさ

肺の大きさは、臓器提供者（ドナー）及び移植希望者（レシピエント）の年齢区分に応じ、下記の方法で評価する。

1）臓器提供者（ドナー）及び移植希望者（レシピエント）がいずれも18歳以上の場合

（予測ＶＣＤ[注1)]／予測ＶＣＲ[注2)]－1）×100の値（%）で判断する。

① 片肺移植の場合 －30～30%

② 両肺移植の場合 －30～30%

注1） 予測ＶＣＤ：臓器提供者（ドナー）の予測肺活量

注2） 予測ＶＣＲ：移植希望者（レシピエント）の予測肺活量

予測肺活量の計算式

（男性） 予測肺活量（L）＝0.045×身長（cm）－0.023×年齢－2.258

（女性） 予測肺活量（L）＝0.032×身長（cm）－0.018×年齢－1.178

（日本呼吸器学会肺生理専門委員会 2001年4月）

2）臓器提供者（ドナー）及び移植希望者（レシピエント）がいずれも18歳未満の場合

（臓器提供者（ドナー）の身長／移植希望者（レシピエント）の身長－1）×100の値（%）で判断する。

① 片肺移植の場合 －12%～15%

② 両肺移植の場合 －12%～12%

3）臓器提供者（ドナー）及び移植希望者（レシピエント）の年齢が1）又は2）の場合に該当しない場合

（臓器提供者（ドナー）の身長／移植希望者（レシピエント）の身長－1）×100の値（%）で判断する。

① 片肺移植の場合 －12%～15%

② 両肺移植の場合 －12%～12%

（3）前感作抗体

ダイレクト・クロスマッチを実施し、陰性であることを確認する。

パネルテストが陰性の場合、ダイレクト・クロスマッチ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）の肺を摘出してから８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が表示されていた場合には、当該親族を優先する。

（2）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）待機期間

待機期間の長い患者を優先する。

（4）肺の大きさ

前提条件（2）肺の大きさの1）又は2）の場合を優先する。

（5）術式による優先順位

術式は、片肺移植、両肺移植の２種類とし、第１術式、第２術式の２つまで登録可能とする。

術式による優先順位は次のとおりとする。

1）　臓器提供者（ドナー）の両肺が利用できる場合であり、第１優先順位の選択を行った結果、

①　第１術式に係る両肺移植希望者（レシピエント）が、第１優先順位となれば、当該両肺移植希望者（レシピエント）を選択する。

② 第１術式に係る片肺移植希望者（レシピエント）が第１優先順位となれば、第１術式に係る片肺移植希望者（レシピエント）で次の順位に位置する者とそれを分けあうこととする。次順位に位置する第１術式に係る片肺移植希望者（レシピエント）が選択されない場合には、第２術式に係る片肺移植希望者（レシピエント）の中で優先順位の高い者と分け合うこととする。

③ 第１術式に係る片肺移植希望者（レシピエント）が第１優先順位となり、第１術式、第２術式を考慮しても片肺移植希望者（レシピエント）が１名のみである場合、

○当該片肺移植希望者（レシピエント）が第２術式として両肺移植を希望していれば、当該移植希望者（レシピエント）を選択し（注１）、

○当該片肺移植希望者（レシピエント）が第２術式として両肺移植を希望していなければ、両肺移植希望者（レシピエント）の中で優先順位の高い者を選択する（注２）。ただし、当該片肺移植希望者（レシピエント）が優先すべき親族であるときは、当該移植希望者（レシピエント）を選択する。

（注１） 当該移植希望者（レシピエント）は必ずしも両肺移植を受ける必要はない。
（注２） この場合に限り、術式を優先し、片肺移植希望者（レシピエント）より両肺移植希望者（レシピエント）を優先する。

２） 臓器提供者（ドナー）の片肺のみが利用できる場合には、第１術式に係る片肺移植希望者（レシピエント）の中から優先順位の高い者を選択する。第１術式に係る片肺移植希望者（レシピエント）が選択されない場合には、第２術式に係る片肺移植希望者（レシピエント）の中から優先順位の高い者を選択する。

３） １）、２）の結果、ＡＢＯ式血液型が一致する移植希望者（レシピエント）が選択されない場合、ＡＢＯ式血液型が適合するものについて１）、２）と同様の手順により移植希望者（レシピエント）を選択する。

３．その他

（１）臓器提供者（ドナー）又は移植希望者（レシピエント）が６歳以上18歳未満の場合、その予測肺活量については、以下の計算式を参考とすることができる。

予測肺活量の計算式（6歳以上18歳未満の場合）

（男性） 予測肺活量（L）＝2.108－0.1262×年齢＋0.00819×年齢^2
－3.118×身長（m）＋2.553×身長（m）^{2}

（女性） 予測肺活量（L）＝1.142－0.00168×年齢^2－2.374×身長（m）
＋2.116×身長（m）^{2}

（日本小児呼吸器疾患学会肺機能委員会 2008 年）

（2）基礎疾患、重症度などによる医学的緊急度は、将来考慮されるべきである。
また、この基準は実績を踏まえて見直しを行う必要がある。

日本人小児スパイログラム基準値(6～18歳)

日本小児呼吸器疾患学会肺機能委員会2008年策定

		定数項	Aの係数	A^2の係数	AHの係数	Hの係数	H^2の係数	R^2
		a	b	c	d	e	f	
男	FVC	2.108	−0.1262	0.00819	−	−3.118	2.553	0.9122
	FEV_1	3.347	−0.1174	0.00790	−	−4.831	2.977	0.9189
	MMF	3.166	−0.6008	−	0.4744	−0.957	−	0.7604
	PEF	3.987	−0.9408	0.01313	0.5811	−	−	0.8201
	V_{50}	2.043	−0.4953	−	0.4063	−	−	0.7440
	V_{25}	4.709	−0.4459	−0.01330	0.5593	−3.888	−	0.6845
女	FVC	1.142	−	0.00168	−	−2.374	2.116	0.8421
	FEV_1	1.842	−	0.00161	−	−3.354	2.357	0.8572
	MMF	4.148	−	0.00269	−	−6.488	3.636	0.6598
	PEF	4.545	−	0.00429	−	−7.343	4.637	0.6382
	V_{50}	3.492	−	0.00309	−	−5.337	3.267	0.6355
	V_{25}	3.076	−	0.00133	−	−5.010	2.656	0.5346

予測式　$a + b \times A + c \times A^2 + d \times AH + e \times H + f \times H^2$

A:年齢(歳)，　H:身長(m)，　R^2:自由度修正済み決定係数

参考資料1

参考資料２

日本呼吸器学会肺生理専門委員会報告

日本人のスパイログラムと動脈血液ガス分圧基準値

日本呼吸器学会肺生理専門委員会

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日本呼吸器学会肺生理専門委員会

2001年4月

はじめに

スパイログラムと血液ガス測定は呼吸器疾患のみに限らず日常診療においてルーチン検査として行われている基本的検査項目である．利用に際して基準値が必要であるが本学会肺生理専門委員会より1993年2月基準値が発表されたが，この基準値は高齢者数が少ないこととスパイログラムの表示を身長で割った値として出しているため[1]，世界的に身長と年齢の関数として計算している出し方ではないことから，我が国のスパイロメーター各機器には採用されておらず，欧米人の基準値が採用されている．基準値は経年的に身長と寿命も変化しているため，1993年の基準値より，8年後の2000年の基準値を再検討して少しでも現在に近づけることを今回の目的とした．更に10年後新たな基準値を後進の人達が作成すると考えられる．

高齢者の診療が増えているが，高齢者で完全に健康である人はまれである．被験者が完全に健康であると申告をしても老年者では特に無自覚疾病があるかもしれず，腎機能低下もあるかもしれない．不顕性脳血管障害は65歳以上の約半分にみられるという．被験者をすべて検査してから正常者と診断する方法では千人単位の基準値を出すには不合理である．欧米の既報告の基準値でも同様の扱いをしている．本委員会ではスパイログラムと血液ガスに影響を与えると報告されている疾患を有している被験者を除いて，人間ドックや病院で呼吸器とは無関係の部位の術前検査などで測定した値とした．この方法は1993年の本委員会が集積したと同様の基準でもある．このため欧米で既報告の基準値を作成した住民検診よりむしろ，過去に症状があった気管支喘息や気管支拡張症などを厳密に除外できた分被験者が医師の診察を通過している分今回の基準値では異常値を排除できている可能性が高いと考えられる．

臨床検査の正常値の概念は平均値±2 SDから外れた5%の人達を異常と認識する方法であるため不合理であると考えられるようになっている．むしろ，ある程度の問診や診察によって選別された被験者を対象とした検査値を基準値と呼称する方法がとられるようになっている．被験者が厳しく限定されたのが基準値とされている．本検査でも，この方法に従い基準値とした．

喫煙は諸々の呼吸器疾患を引き起こす．喫煙は約15%の人に慢性閉塞性肺疾患を生じさせ，残りの85%の人にも多かれ少なかれ閉塞性障害を引き起こす[2]．従って，喫煙者の基準値は重症から軽症の閉塞性障害まで広く分布しているため作成しても意味がないため非喫煙者のみとした．過去に喫煙歴のある人も除外した．

1. 方法

被験者は日本呼吸器学会肺生理専門委員会の委員より集積した1,838名である．年齢は18歳から95歳まで分布している．非喫煙者で過去に喫煙既往歴のない以下の被験者を選択した．

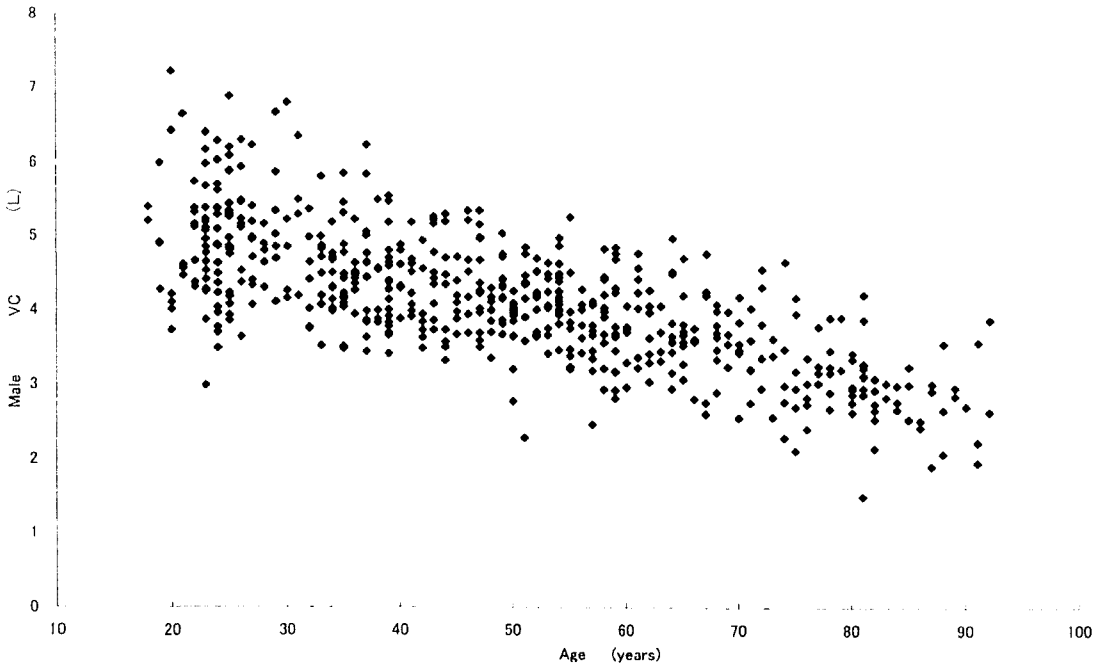

図1 男性における年齢と肺活量（VC）の関係

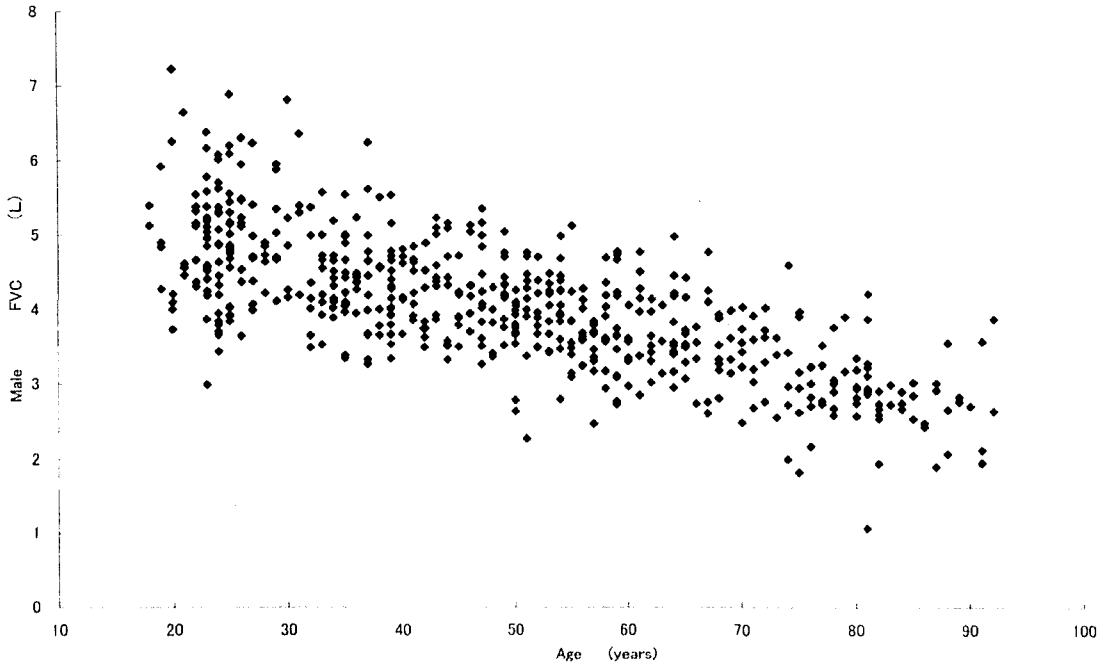

図2 男性における年齢と努力肺活量（FVC）の関係

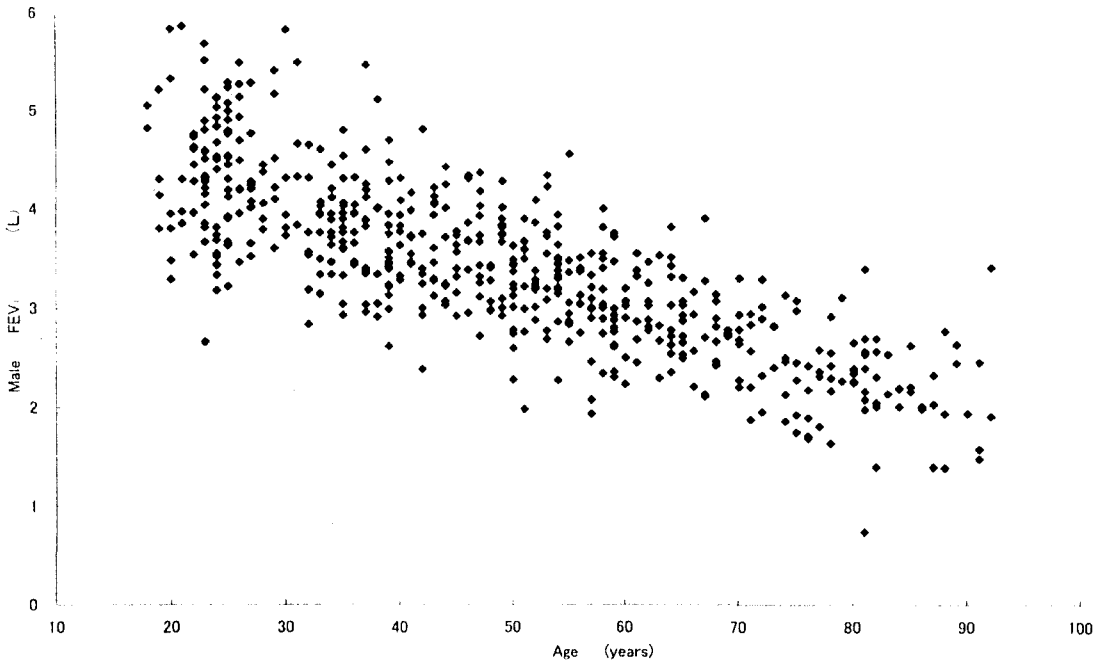

図3 男性における年齢と一秒量（FEV_1）の関係

1）過去及び現在において心肺疾患を有せず，現在呼吸器症状（喘鳴・咳・痰・労作時息切れ）のない人.

2）肥満を除外する(標準式より 120 強を肥満という).

3）神経筋疾患や円背など胸郭障害を除外する.

4）歩いて測定所（病院・施設・保健所）へ行ける人.

5）重症の痴呆症なく，スパイログラムが出来る人.

6）腎不全・肝不全などの重症例を除外する.

7）インシュリン治療中の糖尿病や症状のある副鼻腔

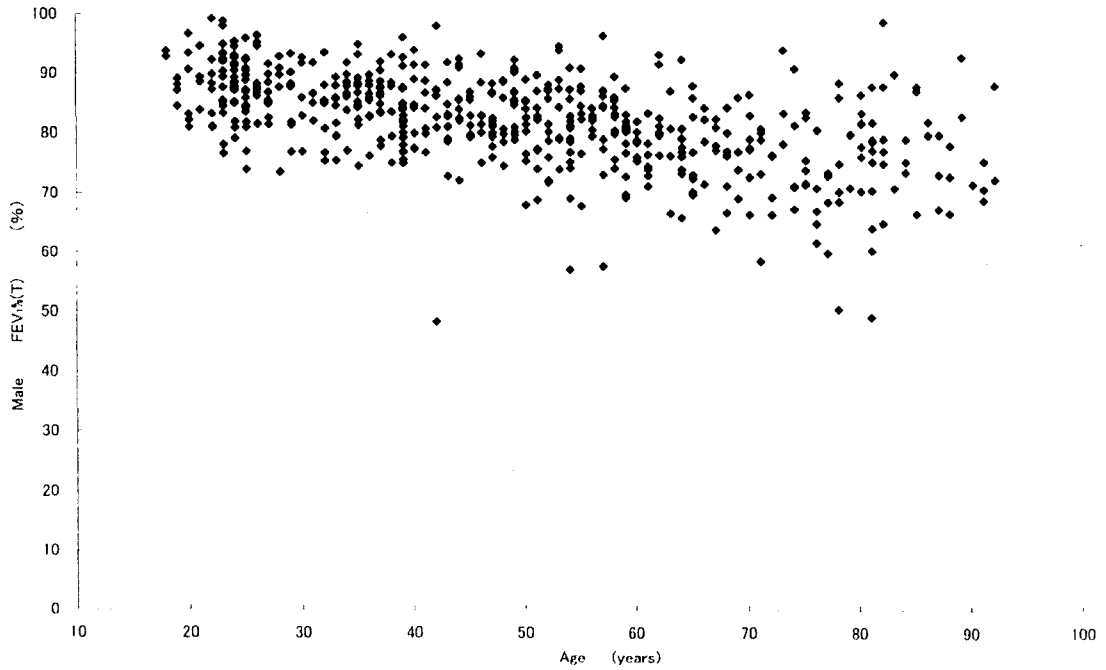

図 4 男性における年齢とテフノーの一秒率（$FEV_1\%$（T））の関係

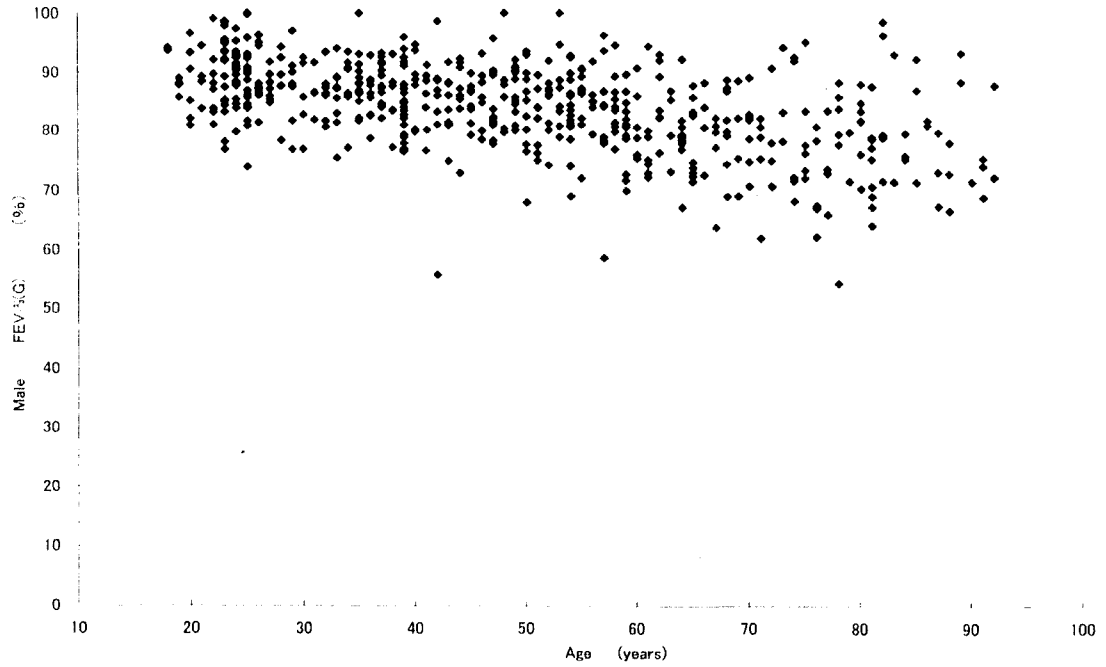

図 5 男性における年齢とゲンズラーの一秒率（FEV_1（G））の関係

炎等肺機能に影響を及ぼすと考えられる疾患は除く.

8）ただし以下の者は入れる. 高血圧・不全麻痺のない脳血管障害・耳鼻科・眼科・皮膚科領域疾患・その他の局所疾患・内分泌疾患・糖尿病・精神疾患・消化器疾患・四肢障害・局所の癌.

これらの被験者は人間ドックや術前検査などで行った過去 10 年間のものとした.

プロトコールは医師又は検査技師が検査を実施した成

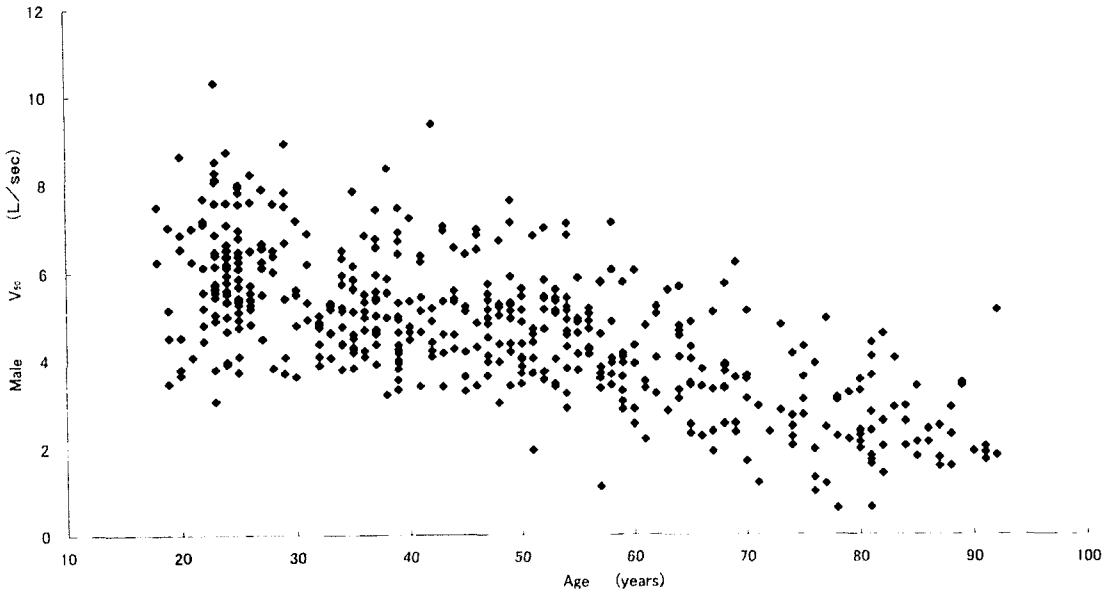

図6 男性における年齢と50% FVC におけるフロー（V̇50）の関係

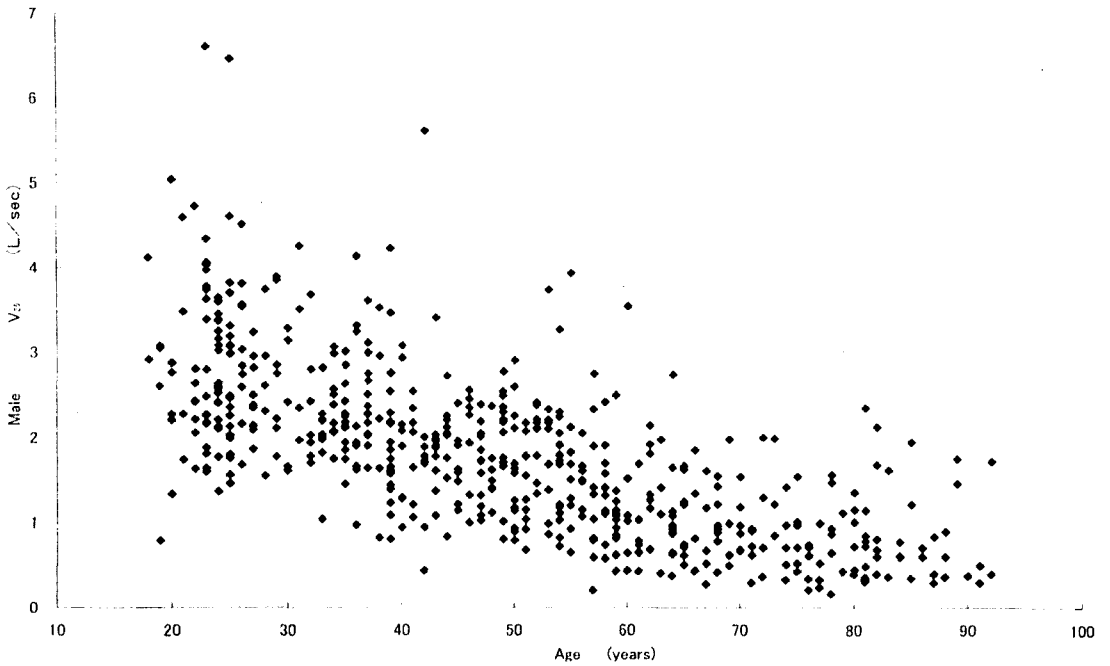

図7 男性における年齢と25% FVC におけるフロー（V̇25）の関係

績とし，スパイログラムと血液ガス測定である．スパイログラムにはフローボリウム曲線も含まれる．測定は原則として座位，但し，スパイログラムは立位及び血液ガス分圧測定は仰臥位でも可とした．スパイログラムと血液ガス測定は同一人又は別々の被験者で測定した．スパイログラムは3回行い，その内の最大値を採用した．スパイログラムはボリウム型とフロー型いずれでもよく，血液ガス測定と共にJIS規格検定合格ずみで市販されている機器を用いた．測定は日中午前9:00から午後4:00までに行ったものとした．

スパイログラムは肺活量（Vital capacity，VC）を3回行い，次いで努力肺活量(forced vital capacity，FVC)

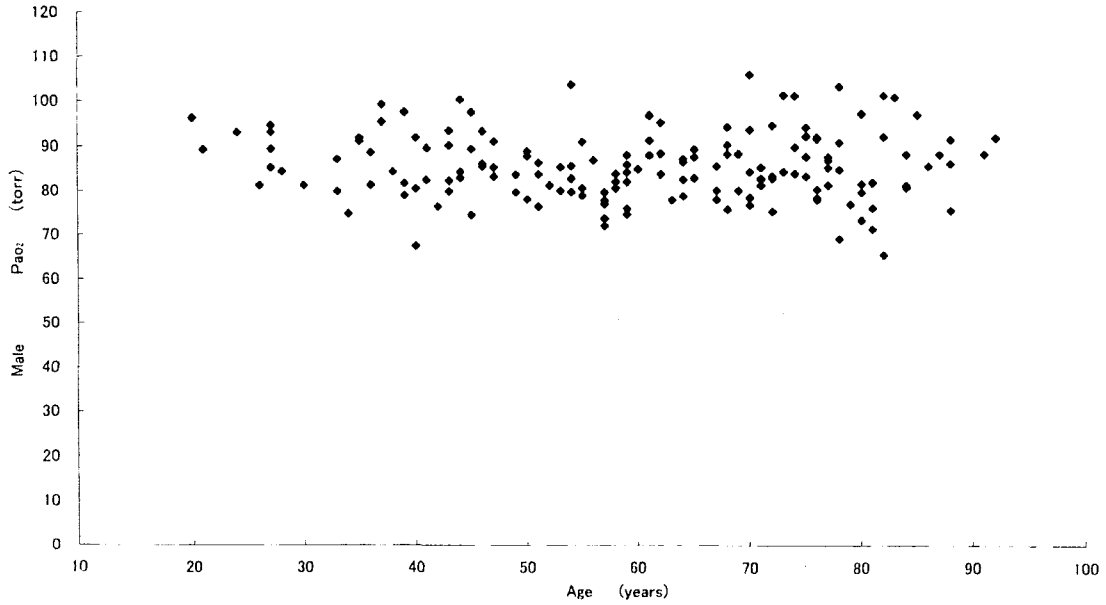

図8 男性における年齢と動脈血酸素分圧（PaO_2）の関係

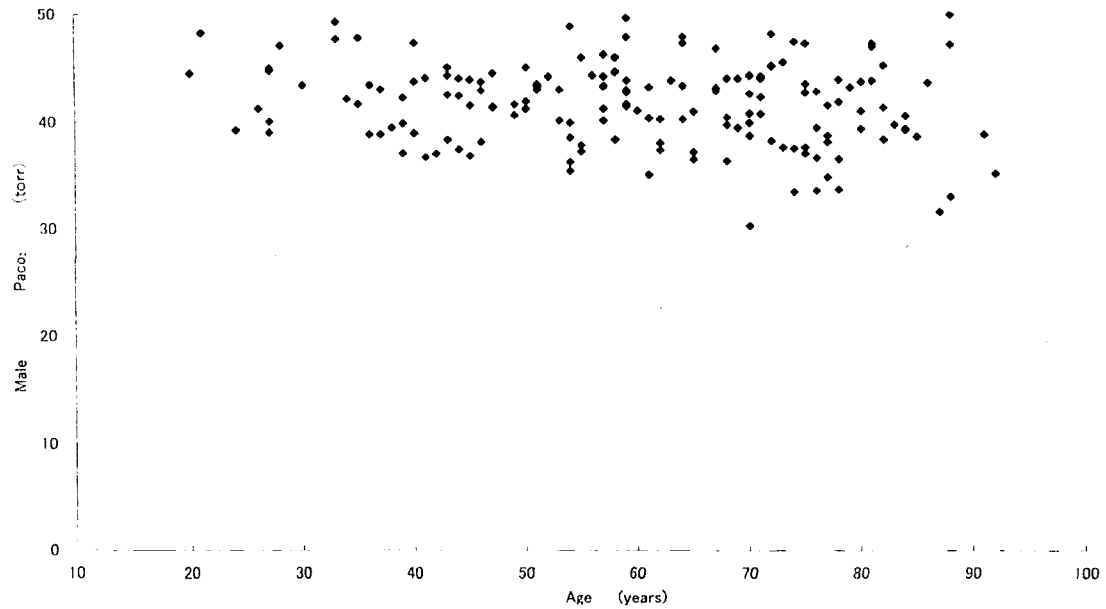

図9 男性における年齢と動脈血炭素ガス分圧（$PaCO_2$）の関係

を3回行い，フローボリウム曲線の形を参考にして満足できる値から最大値を求めた．一秒量(forced expiratory volume at one second，FEV 1）も測定した．

血液ガス測定は被験者が30分以上安静を保ち，上腕動脈又は大腿動脈より採血した．肺胞気動脈血酸素分圧較差（A-aDo 2）は$150-(PaO_2+PaCO_2/0.83)$の簡便式より計算した．

予測式を得るために重回帰分析を行い，各変数の寄与率を算出し，これに従って予測式を設定した．

2. 結果

スパイログラムの成績は男性584名，女性1,227名集計され，血液ガス測定は男性164名，女性769名集計された．スパイログラムでは閉塞性障害患者においてしばしば見かける現象はVCがFVCより大きいことが多い．しかし，健常者特に高齢者では手技の不慣れ等によ

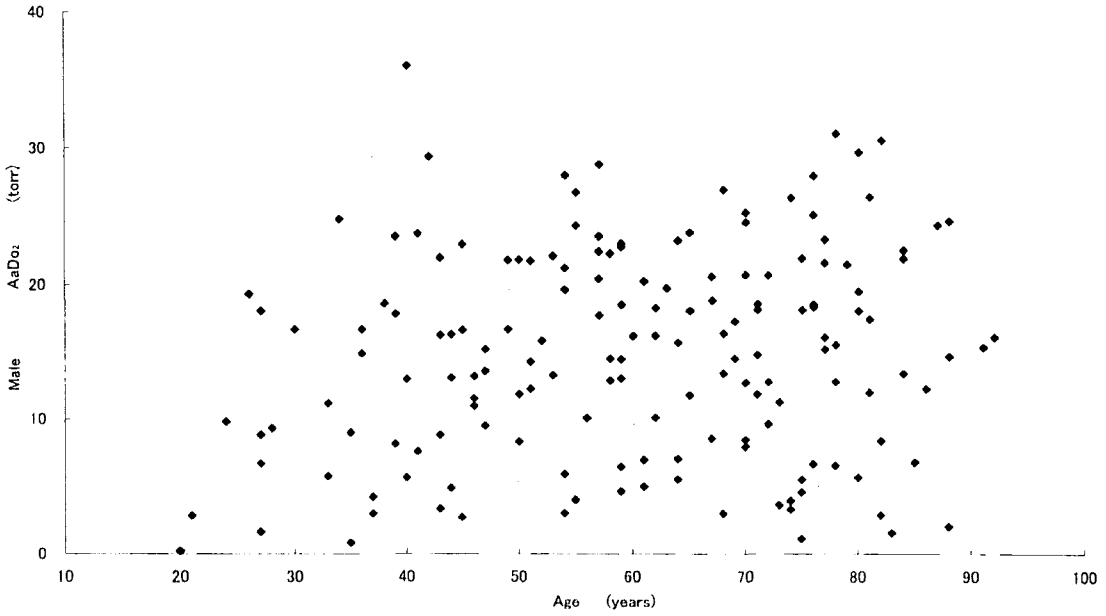

図 10 男性における年齢と肺胞気動脈酸素分圧の較差（A-aDO$_2$）の関係

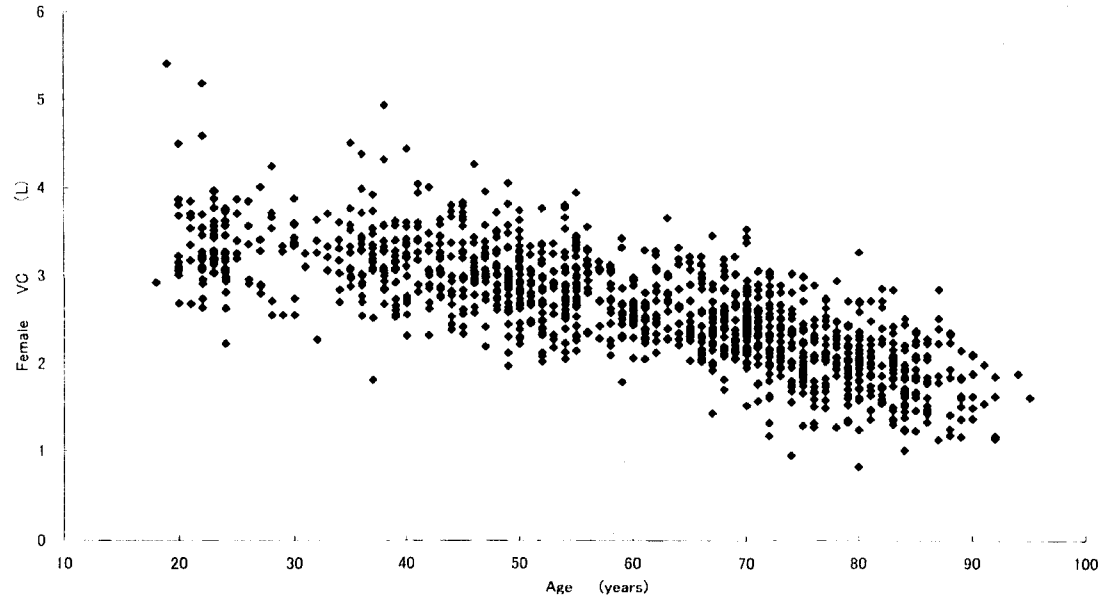

図 11 女性における年齢と肺活量（VC）の関係

りFVCがVCより大きいことも少なくない．臨床的にはこのような時いかなる被験者の努力であれ値の大なる方をその人のVCととる方が役立つことから，本委員会でもFVCがVCより大なる時はFVCをVCの値とした．逆にFVCがVCより小さい時はそのままの値とした．従って，FVCは一切補正をしなかった．FVCがVCを上回る値は男女共ほとんどが0.2 L以内にとどまり最大でも0.6 L以内であった．男性ではこのような補正をした人が84名（14%），女性では283名（23%）であった．

血液ガス値ではA-aDO$_2$を算出した際マイナスの値をとる例が男性22名（13%），女性37名（5%）見られた．A-aDO$_2$マイナス例はほとんどが10 torr以内であり，最大で30 torrであった．マイナス例は以後の成績より

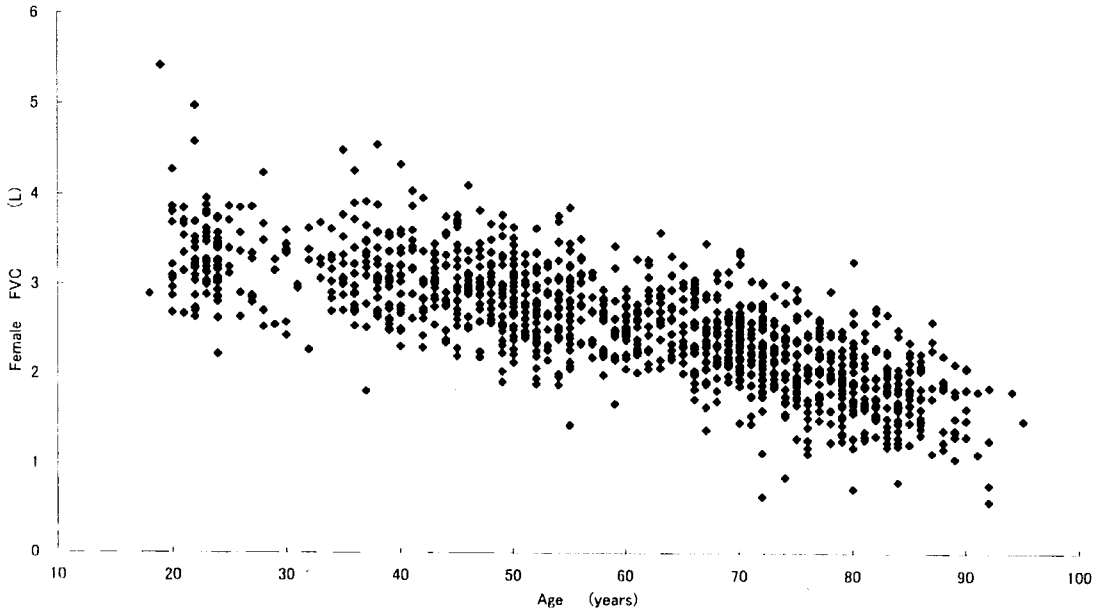

図 12　女性における年齢と努力肺活量（FVC）の関係

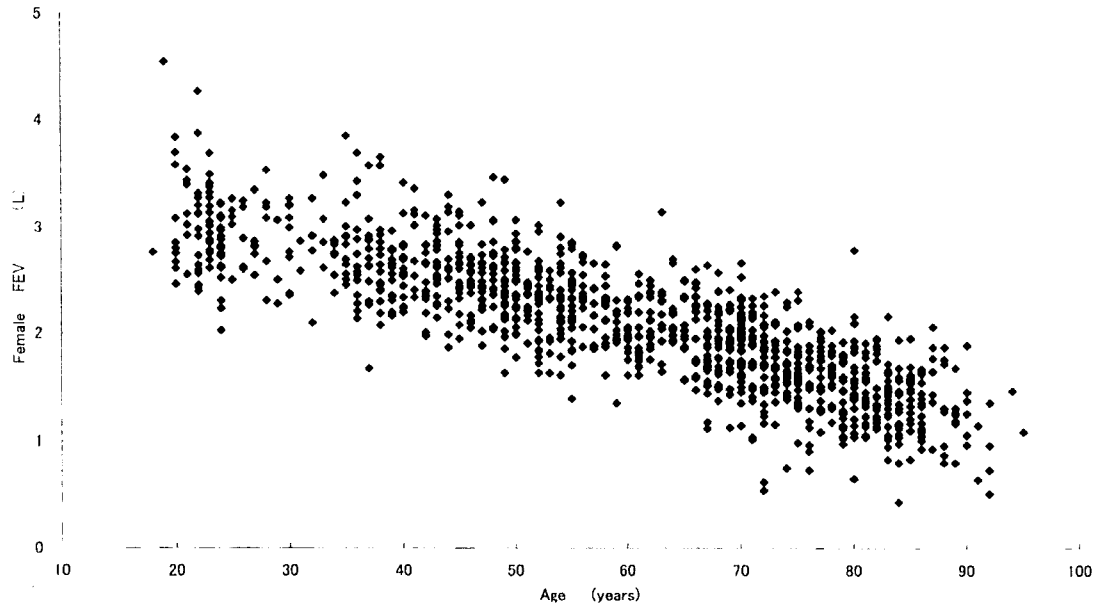

図 13　女性における年齢と一秒量（FEV_1）の関係

消去した.

成績の合計集積名は延べ 1,897 名であるが，A-aDO_2 のマイナス値を示した人数男女合計 59 名を除いた 1,838 名について解析した.

以後，スパイログラムと血液ガスの成績を男性，女性の順に年齢に対してどのように分布しているのかを示す．図 1 は男性 VC と年齢の関係を示す．図 2 は男性 FVC と年齢の関係を示す．図 3 は男性 FEV_1 と年齢の関係を示す．一秒率（Forced expiratory volume at one second，FEV_1%）は FEV_1/VC（%）で求めるテフノーの一秒率(Tiffeneau，T の一秒率，FEV_1%(T))と FEV_1/FVC（%）で求めるゲンズラーの一秒率（Gaensler，G の一秒率，FEV_1%（G))がある．図 4 は男性の FEV_1%（T）と年齢の関係を示す．図 5 は男性の FEV_1（G）と

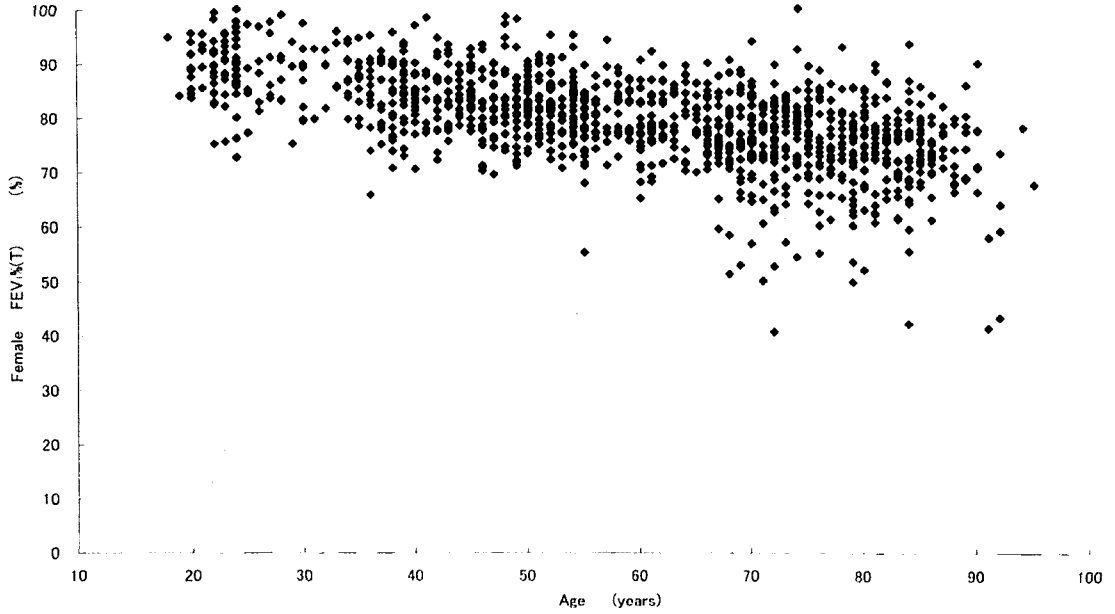

図 14 女性における年齢とテフノーの一秒率（FEV_1% (T)）の関係

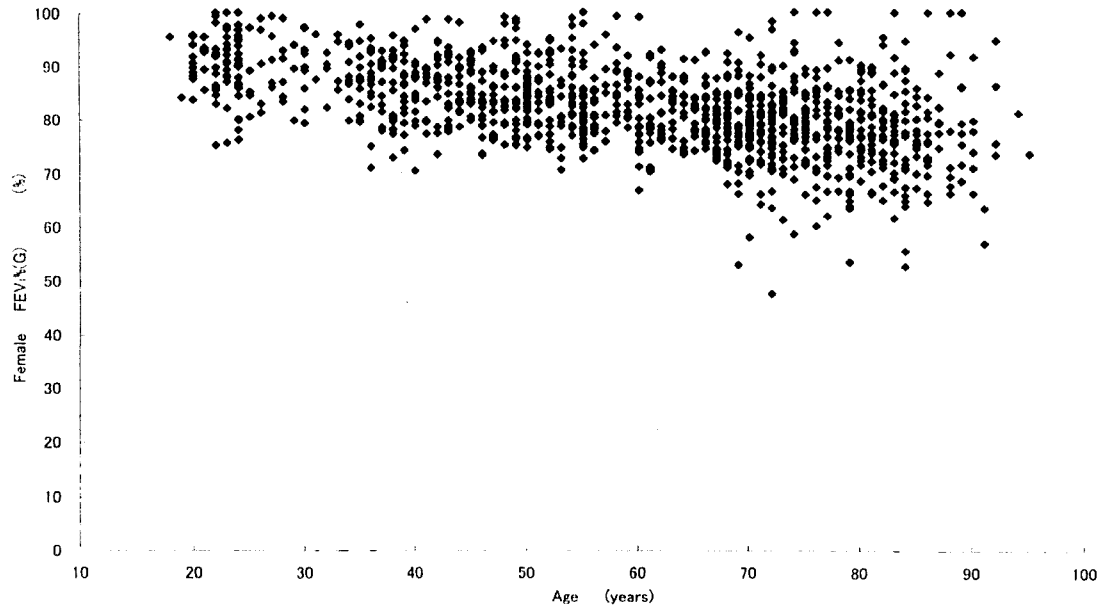

図 15 女性における年齢とゲンズラーの一秒率（FEV_1% (G)）の関係

年齢の関係を示す．図 6 は男性のフローボリウム曲線の 50% 肺活量でのフロー（$\dot{V}50$）と年齢の関係を示す．図 7 は同じく 25% 肺活量でのフロー（$\dot{V}25$）と年齢の関係を示す．図 8 は男性の動脈血酸素分圧（PaO_2）と年齢の関係を示す．図 9 は男性の動脈血炭素ガス分圧（$PaCO_2$）と年齢の関係を示す．図 10 は男性の $A\text{-}aDO_2$ と年齢の関係を示す．

図 11 は女性の VC と年齢の関係を示す．図 12 は女性の FVC と年齢の関係を示す．図 13 は女性の FEV_1 と年齢の関係を示す．図 14 は女性の FEV_1% (T) と年齢の関係を示す．図 15 は女性の FEV_1% (G) と年齢の関係を示す．図 16 は女性の $\dot{V}50$ と年齢の関係を示す．図 17 は女性の $\dot{V}25$ と年齢の関係を示す．図 18 は女性の PaO_2 と年齢の関係を示す．図 19 は女性の $PaCO_2$ と年齢の関

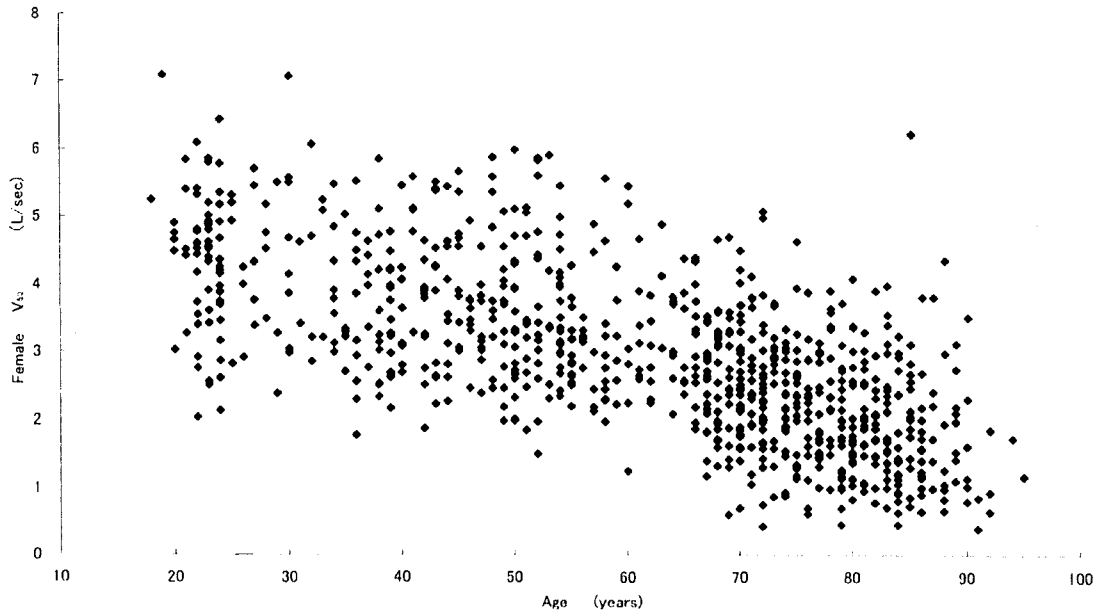

図 16　女性における年齢と 50% FVC におけるフロー（$\dot{V}50$）の関係

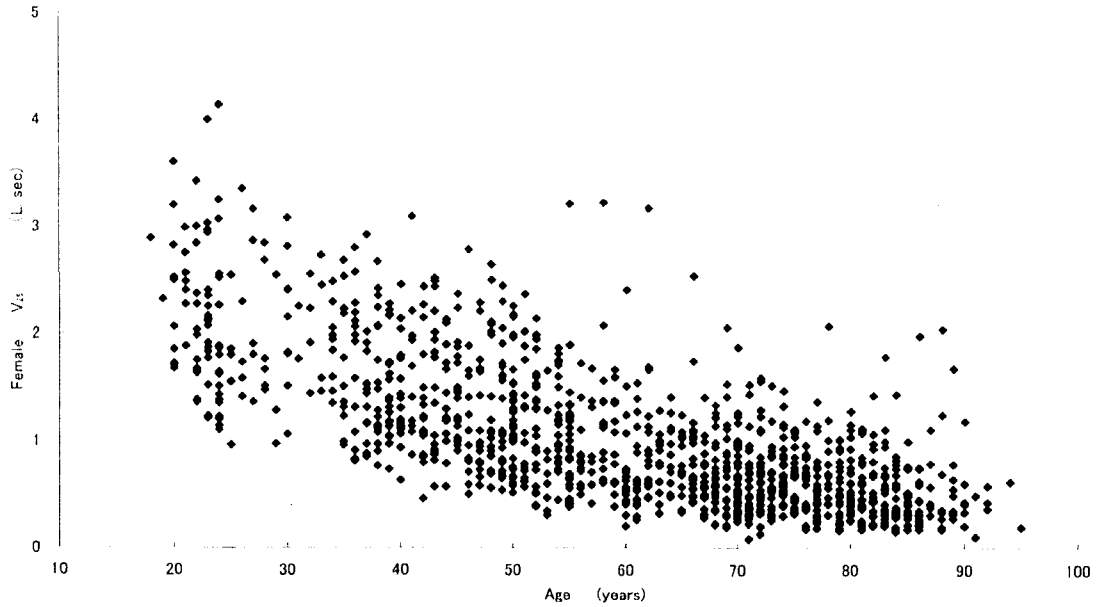

図 17　女性における年齢と 25% FVC におけるフロー（$\dot{V}25$）の関係

係を示す．図 20 は女性の A-aDO_2 と年齢の関係を示す．

以上の図 5 から図 20 までの平均値±SD を表 1 に示す．18 歳と 19 歳は人数も少ないため 29 歳以下の群に含め，90 歳から 95 歳までは人数も少ないため 80 歳以上に含めた．

各値に，年齢と身長を加え各指標間の相関係数を表 2 にした．表 2 は男女を一緒にみたものである．$PaCO_2$ を除いて各値は有意な相関を示した．又，身長はスパイログラムの各値とは有意な相関を示したが，血液ガス各値とは相関は低かった．

性，年齢，身長を独立変数とした重回帰分析を表 3 に行った．性（男性を 1，女性を 0 とするダミー変数）・年齢・身長を独立変数とし，各値を従属変動として重回帰分析をすると表 3 の如くで性別はスパイログラムに寄

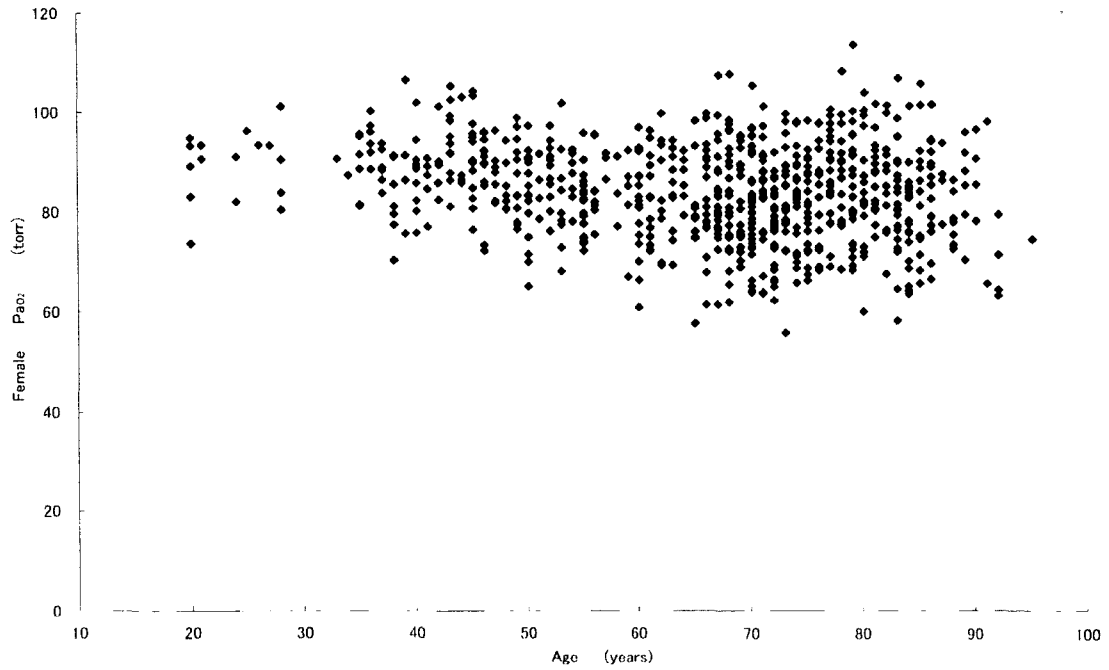

図 18　女性における年齢と動脈血酸素分圧（PaO_2）の関係

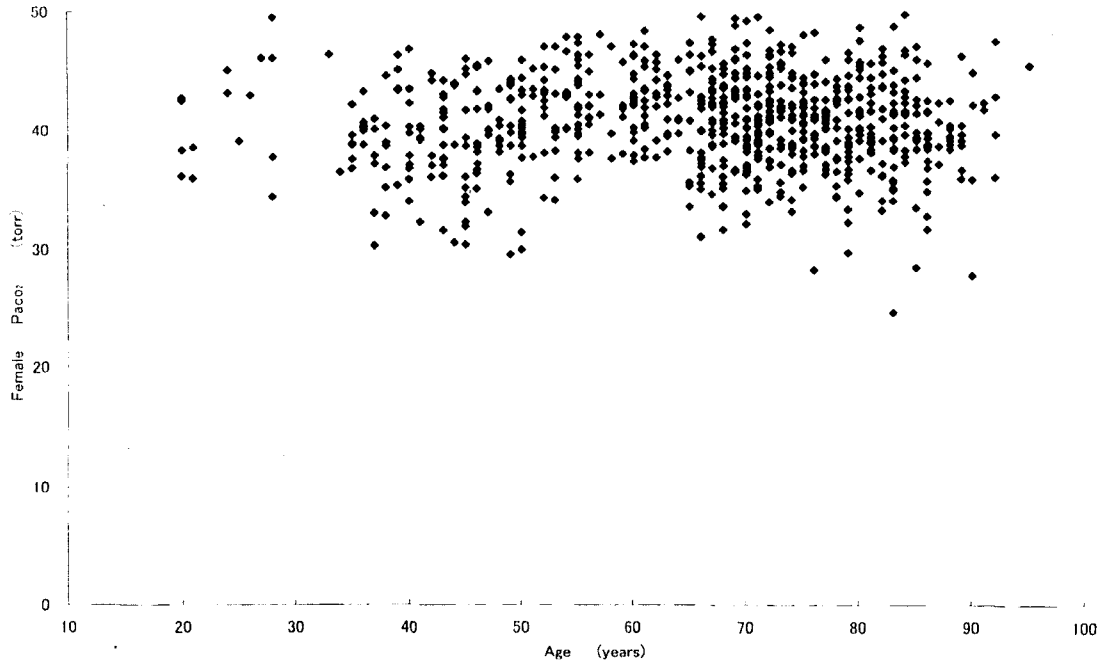

図 19　女性における年齢と動脈血炭酸ガス分圧（$PaCO_2$）の関係

与率が高く，年齢と身長も比較的寄与率も高かった．血液ガス値はスパイログラム程性別・年齢・身長の寄与率は高くなかった．）

表3の寄与率を基に肺機能検査予測式を作成し，表4に示した．スパイログラムに関しては性の寄与率が高く，ついで身長・年齢の順であった．そのため，性別に身長と年齢の2変数の重回帰式で予測式を作成した．即ち y =a×身長（cm）+ b×年齢＋定数から表4より求めるス

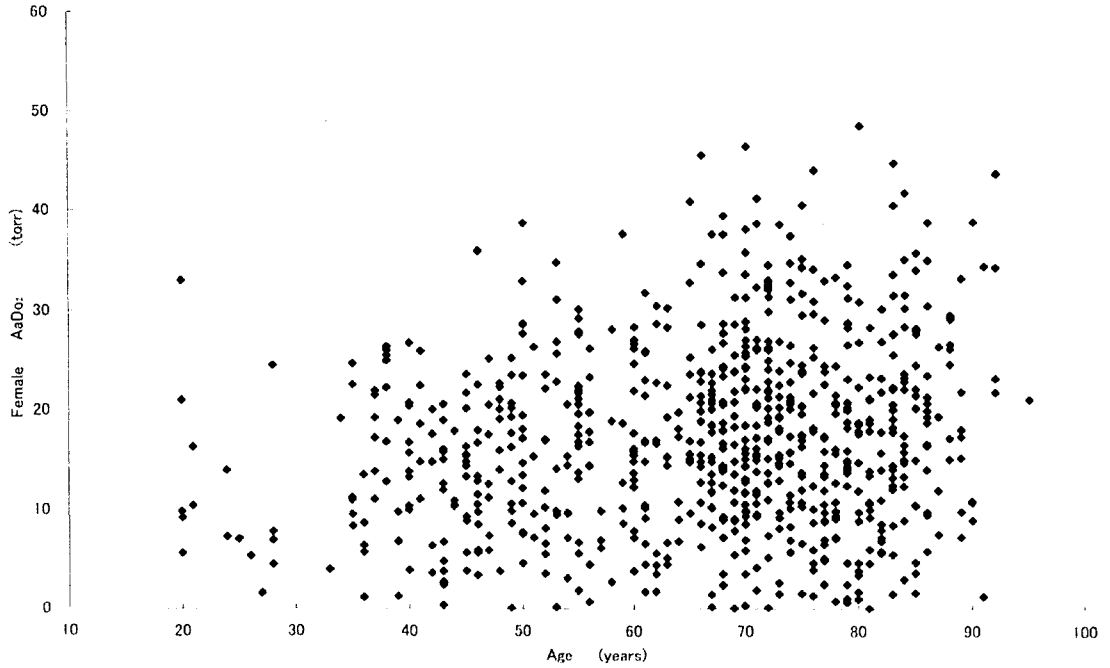

図 20 女性における年齢と肺胞気動脈血酸素分圧の較差（A-aDO$_2$）の関係

パイログラムの値を得る方法である．一方血液ガスでは年齢と身長の寄与率が低かったが，同様の予測式を求めた．図 21 は，表 4 の成績を肺活量と一秒量のノモグラムにした図である．非喫煙者の男女別に年齢と身長から予測値を知ることができる．

3. 考察

基準値で本稿ではとり上げないもう一つは個人の基準値である．同一人を対象とした値は狭い範囲で変動している．例え集団から求められた基準値内に個人の値があっても個人の以前に測定した基準値より大きく逸脱して異常値となっていることもある．肺は腎と共に最も加齢の影響を受けやすい臓器のため 20 歳代のとき個人の基準値をとっておくことはその人の異常検出に役立つことは明らかであろう．このように集団の基準値から個人の異常を検出するには大いなる限界がある．

測定時の体位の影響は呼吸器疾患のない被験者では小さい．スパイログラムでは仰臥位で測定した一秒量と一秒率は立位での測定値に比較して小さいことが知られている．又，肺活量・努力肺活量は仰臥位で立位よりも 7～8% 低値を示し，更に座位では立位よりも 1～2% 低い値をとるとの報告がある[3]．患者を対象としたスパイログラムでは，立位での検査が困難あるいは危険な場合もあるので米国胸部疾患学会は，立位あるいは座位のいずれで検査しても良いとしている．ただし仰臥位のみは特別の理由を付し 7～8% の差を考慮に入れる必要がある[1]．

肺気量の測定機器の精度は 0.5 L から 8 L の範囲で測定できる事と，測定誤差は±3% 以内又は±0.05 L 以内に設定されている．立位と座位の差 1～2% は測定機器の誤差範囲内であり，スパイログラムの基準値を立位と座位とを別々に測定することの特に老年者での困難上からも立位か座位であれば同一の基準値を用いた方が臨床上実用化できると考えられ，本稿ではいずれでもよいとした．

体位の影響は血液ガス測定においても起こりうる．立位や座位から仰臥位にすると，安静呼気位が小さくなり，末梢気道が閉塞する可能性が指摘されている．特にこの影響は肥満者で大きい．この分 PaO_2 が低下する場合が閉塞性障害を持つ被験者には指摘されている．しかし，血液ガス採血は立位では一般に採血せず，安静を重視することから座位又は仰臥位で採血されているのが現状である．本基準値でも，これまでの慣習に従い座位または仰臥位で採血した値とした．臨床上，血液ガス採血時の体位を座位と仰臥位との微妙な差を問題にすることはほとんど生じず，特別な場合のみ体位を付記して考慮する必要がある．

A－aDO$_2$ は臨床上計算式を用いて求めることになっているが，マイナス値が男性 12% 女性 4% に見られた．あくまでも定常状態で採血するのが原則であるが，採血時の痛みから息苦しさや過換気などがあるとマイナスも生じうる．これらの値は少なくとも異常に大きい値とは

表1　性別・年齢別肺機能検査平均値と標準偏差値(± SD)

スパイログラム

年齢階層 歳	人数	%	年齢 歳	身長 cm	VC L	FVC L	FEV_1 L	FEV_1%(T) %	FEV_1%(G) %	VC_{50} L/sec	L_{25} L/sec
男性											
18～29	119	20.4	24.13	171.64	4.96	4.89	4.35	87.96	89.25	6.02	2.84
			(2.54)	(6.20)	(0.79)	(0.78)	(0.64)	(5.54)	(5.55)	(1.37)	(0.98)
30～39	100	17.1	35.42	171.54	4.52	4.43	3.85	85.22	87.06	5.08	2.34
			(2.75)	(5.38)	(0.68)	(0.68)	(0.58)	(4.57)	(4.24)	(1.08)	(0.67)
40～49	92	15.8	44.99	170.21	4.29	4.20	3.62	84.59	86.41	5.07	1.98
			(2.96)	(5.79)	(0.53)	(0.53)	(0.43)	(4.85)	(4.95)	(1.08)	(0.67)
50～59	112	19.2	54.33	167.82	3.93	3.81	3.22	82.05	84.65	4.49	1.64
			(2.87)	(6.92)	(0.54)	(0.54)	(0.49)	(6.36)	(6.12)	(1.08)	(0.66)
60～69	66	11.3	64.66	163.73	3.68	3.57	2.88	78.49	80.96	3.73	1.19
			(2.83)	(4.83)	(0.54)	(0.55)	(0.39)	(5.88)	(6.72)	(1.14)	(0.62)
70～79	48	8.2	74.58	160.82	3.22	3.11	2.39	74.42	77.43	2.75	0.85
			(2.84)	(7.05)	(0.58)	(0.62)	(0.48)	(9.57)	(9.78)	(1.14)	(0.44)
80～	47	8.0	84.47	156.80	2.84	2.79	2.19	76.57	78.25	2.53	0.79
			(3.88)	(8.60)	(0.53)	(0.56)	(0.49)	(9.28)	(8.30)	(0.95)	(0.52)
女性											
18～29	101	8.2	23.52	157.86	3.38	3.33	2.99	88.68	89.83	4.34	2.09
			(2.31)	(6.21)	(0.52)	(0.52)	(0.44)	(6.00)	(5.92)	(1.03)	(0.69)
30～39	108	8.8	35.51	158.07	3.23	3.15	2.74	85.07	87.20	3.80	1.77
			(3.00)	(5.42)	(0.45)	(0.43)	(0.37)	(6.64)	(6.34)	(1.05)	(0.58)
40～49	178	14.5	44.82	156.89	3.04	2.97	2.56	84.40	86.47	3.75	1.43
			(2.89)	(5.58)	(0.41)	(0.41)	(0.36)	(5.44)	(5.95)	(0.97)	(0.56)
50～59	196	16.0	53.66	154.00	2.80	2.69	2.29	82.20	85.57	3.40	1.24
			(2.78)	(4.62)	(0.37)	(0.40)	(0.29)	(5.84)	(6.29)	(0.98)	(0.54)
60～69	194	15.8	65.86	150.67	2.52	2.45	1.99	79.06	81.33	2.87	0.88
			(2.69)	(4.99)	(0.39)	(0.40)	(0.34)	(6.69)	(6.38)	(0.89)	(0.46)
70～79	264	21.5	74.16	147.42	2.18	2.11	1.65	75.42	78.44	2.32	0.66
			(2.98)	(5.79)	(0.43)	(0.44)	(0.35)	(8.18)	(8.03)	(0.87)	(0.34)
80～	186	15.2	84.17	143.58	1.86	1.77	1.36	72.96	77.05	1.88	0.54
			(3.32)	(6.50)	(0.38)	(0.39)	(0.33)	(9.28)	(9.72)	(0.89)	(0.34)

( ) 内は± SD

血液ガス分圧

年齢階層 歳	人数	%	年齢 歳	身長 cm	Pao_2 TORR	$Paco_2$ TORR	HCO_3 mEq/l	$AaDo_2$ TORR
男性								
18～29	9	5.5	24.57	171.09	89.51	42.43	25.25	9.37
			(2.99)	(5.91)	(5.17)	(3.50)	(2.10)	(7.15)
30～39	14	8.5	35.85	172.20	86.02	42.02	24.36	13.35
			(2.76)	(8.03)	(7.69)	(3.48)	(1.29)	(7.06)
40～49	24	14.6	44.17	169.48	85.20	41.58	24.75	14.71
			(2.68)	(6.89)	(7.45)	(2.99)	(1.92)	(8.13)
50～59	33	20.1	55.27	164.64	82.22	42.51	25.34	16.57
			(3.07)	(5.03)	(5.98)	(3.43)	(2.21)	(7.20)
60～69	24	14.6	64.75	162.33	85.59	41.17	25.09	14.81
			(2.85)	(4.57)	(5.69)	(3.51)	(1.62)	(6.40)
70～79	38	23.2	74.05	159.16	86.09	40.55	24.47	15.05
			(2.85)	(5.59)	(8.23)	(4.31)	(1.75)	(7.81)
80～	22	13.4	84.05	158.44	84.95	41.01	24.91	15.64
			(3.64)	(7.11)	(9.63)	(4.64)	(2.11)	(8.70)
女性								
20～29	16	2.1	23.47	156.27	89.51	40.42	23.57	11.79
			(3.34)	(4.43)	(7.07)	(3.82)	(2.32)	(8.59)
30～39	32	4.2	36.77	154.70	88.08	39.26	23.54	14.61
			(1.63)	(5.36)	(7.23)	(3.88)	(1.90)	(7.47)
40～49	91	11.8	44.79	155.13	88.61	39.42	24.06	13.89
			(2.89)	(5.09)	(7.44)	(4.00)	(1.89)	(7.04)
50～59	87	11.3	53.72	152.74	83.53	41.54	25.34	16.42
			(2.64)	(4.99)	(7.57)	(3.52)	(2.09)	(9.02)
60～69	155	20.2	65.15	150.73	82.48	41.59	25.07	17.42
			(3.07)	(5.17)	(9.69)	(3.82)	(1.99)	(8.76)
70～79	239	31.1	74.02	147.64	82.69	40.59	24.80	18.41
			(2.99)	(5.80)	(9.73)	(3.67)	(1.98)	(9.60)
80～	149	19.4	84.30	143.85	82.85	40.32	24.94	18.57
			(3.20)	(6.43)	(10.32)	(4.13)	(2.60)	(10.20)

( ) 内は± SD

表2　年齢・身長・肺機能検査の相関係数および有意水準

スパイログラム　　(n=1,811)

	年齢	身長	VC	FVC	FEV_1	FEV_1%(T)	FEV_1%(G)	V_{50}	V_{25}
年齢		−0.642***	−0.716***	−0.721***	−0.780***	−0.594***	−0.531***	−0.701***	−0.739***
身長			0.863***	0.846***	0.842***	0.376***	0.321***	0.672***	0.633***
VC				0.993***	0.972***	0.373***	0.306***	0.757***	0.692***
FVC					0.974***	0.406***	0.285***	0.751***	0.679***
FEV_1						0.564***	0.480***	0.848***	0.802***
FEV_1%(T)							0.868***	0.700***	0.703***
FEV_1%(G)								0.683***	0.728***
V_{50}									0.851***
V_{25}									

血液ガス分圧　　(n=933)

	年齢	身長	Pao_2	$Paco_2$	HCO^3	$AaDo_2$
年齢		−0.531***	−0.167***	−0.017	0.089**	0.179***
身長			0.066*	0.077*	−0.027	−0.107**
Pao_2				−0.285***	−0.252***	−0.868***
$Paco_2$					0.721***	−0.228***
HCO_3						−0.118***
$AaDo_2$						

***：$p<0.0001$　**：$p<0.001$　*：$p<0.05$

とれず，$A\text{-}aDO_2$はゼロに近い正常値と考えられるが血液ガスに関する本基準値から除いた．これは$A\text{-}aDO_2$を計算式から求めた限界を示しておりPaO_2の臨床上の意義を考える上での参考値と考えられる．

スパイログラムでは国際的には身長と年齢の一次式で基準値が設定されている．本稿でも一次式を用いた．しかし，$\dot{V}25$は図7と図17から明らかなように老年者では低い値のまま推移し，年齢と一次関数では表し得ないように見える．65歳以上を見ると男性では（図7）$\dot{V}25$ ≦0.5 L/sの人が30人おり，65歳以上の被験者126人中24%に達している．同様に女性では図17より563人中244人と43%に達している．

気流量の測定誤差は±5%あるいは±0.2 L/s以内である．65歳以上の老年者で異常値を検出するために測定誤差の2.5倍である0.5 L/s以内に24%から43%も含まれる集団から異常と断定することは不可能であることは臨床上指摘されている．

従って，$\dot{V}25$は直線回帰式では表せないし，例え二次式で表したとしても65歳以上で基準値から異常値を判別出来ないため意味が少ないと考えられる．従来，$\dot{V}25$を直線回帰式で表現する方法も採られてきた．それらは1972年[5]と1983年[6]において発表されたが，今日の高齢化社会ではなく80歳以上の症例はほとんど含まれていなかった．実際，一秒量及び一秒率はある年齢以上の高齢者になると，選ばれた老年者のみになるためむしろ上昇してくるという報告もあった[7]．しかし，これらの報告も1975年の成績であり，今日の日本のように高齢化率17%の超高齢化社会では一秒量も一秒率も経年的に変化しており多くの老年者が長寿をうける時代では選ばれた老年者のみではないのが一つの理由かもしれない．しかし，$\dot{V}25$の基準値も参考値として用いられることもあることを予想して一次式を記した．

従来，日本においてどの基準値が採用されてきたのかは定まっていない．多くの基準値予測式があり施設によりまちまちに用いられてきた[8]．中でもBaldwinらの式[9]が最も広く用いられており，自動化された測定装置のコンピューターにもほとんどBaldwinらの式が用いられている．Baldwinらの式は男性16歳から69歳，女性16歳から79歳の被験者より得られている．しかも，仰臥位のスパイログラムの成績である．仰臥位の肺活量は座位又は立位の肺活量に対して7〜8%に低いことと，恐らくは日本人の人種的体型の差もあり，本稿の基準値はBaldwinらの予測値より10ないし15%高値を示す．

それでは，異常値はどこから境界線を引いたらよいのであろうか．一般にはある集団の95%が含まれる値を基準値としている．表4から回帰式が得られており残差標準偏差（RSD）は60%信頼限界を示し，2 RSDをとれば95%信頼限界を示すことになる．

平均±2 SDを基準値とする考え方はあり得るが一方では切りの良い数字で平均値の何%を異常とするという考え方も臨床的には使用されている．VCの80%以下を拘束性障害とする．FEV_1%の70〜80%以下を閉塞

表3　重回帰分析

スパイログラム　　(n=1,811)

項目			標準偏回帰係数	相関係数	寄与率
VC	性別	***	0.376	0.71363	0.525
	年齢	***	−0.020	−0.71642	0.014
	身長	***	0.037	0.85295	0.031
	重相関係数		0.907		
FVC	性別	***	0.740	0.70688	0.523
	年齢	***	−0.020	−0.72059	0.015
	身長	***	0.035	0.84586	0.030
	重相関係数		0.904		
FEV_1	性別	***	0.652	0.68128	0.444
	年齢	***	−0.024	−0.78012	0.019
	身長	***	0.027	0.8423	0.023
	重相関係数		0.922		
$FEV_1\%$(T)	性別		0.728	0.19664	0.143
	年齢	***	−0.257	−0.59397	0.153
	身長		−0.034	0.37645	−0.013
	重相関係数		0.595		
$FEV_1\%$(G)	性別		0.402	0.15652	0.063
	年齢	***	−0.226	−0.531	0.120
	身長		−0.040	0.3212	−0.013
	重相関係数		0.532		
V_{50}	性別	***	0.780	0.51571	0.402
	年齢	***	0.041	−0.70086	0.029
	身長	***	0.025	0.67226	0.017
	重相関係数		0.774		
V_{25}	性別	***	0.334	0.4458	0.149
	年齢	***	−0.027	−0.73896	0.020
	身長	***	0.010	0.63347	0.006
	重相関係数		0.776		

血液ガス分圧　　(n=933)

項目			標準偏回帰係数	相関係数	寄与率
Pa_{O_2}	性別		2.012	0.05217	0.105
	年齢	***	−0.121	−0.16714	0.020
	身長		0.099	0.06642	0.007
	重相関係数		0.180		
Pa_{CO_2}	性別		0.447	0.07889	0.035
	年齢		0.005	−0.01735	0.000
	身長		0.027	0.0772	0.002
	重相関係数		0.088		
HCO_3	性別		0.122	0.01579	0.002
	年齢	*	0.013	0.0894	0.001
	身長		0.003	−0.02738	0.000
	重相関係数		0.094		
$AaDo_2$	性別	*	−2.552	−0.09385	0.239
	年齢	***	0.114	0.17878	0.020
	身長		0.066	−0.10744	−0.007
	重相関係数		0.197		

***：$p<0.0001$　**：$p<0.001$　*：$p<0.05$

性障害とする．PaO_2 70～80 torr 以下を低酸素血症とする．$PaCO_2$ 40±5 torr 以上又は以下を異常とする等である．これらの異常値の目安は平均値がいくらであるかによることは当然である．又，図1から20をみても明らかなように年齢と身長を考慮した切り方があることも当然である．表4はあくまでも60%信頼限界2 RSDであ

表4　肺機能測定値と年齢・身長との回帰式より算出する基準値

スパイログラム

項目	男性(n=584)					女性(n=1,227)				
	a	b	定数	R	RSD	a	b	定数	R	RSD
VC L	0.045	−0.023	−2.258	0.786	0.560	0.032	−0.018	−1.178	0.829	0.370
FVC L	0.042	−0.024	−1.785	0.778	0.573	0.031	−0.019	−1.105	0.827	0.378
FEV_1 L	0.036	−0.028	−1.178	0.842	0.470	0.022	−0.022	−0.005	0.873	0.315
$FEV_1\%(T)$ L	0.000	−0.215	93.216	0.555	6.246	−0.063	−0.283	106.223	0.583	7.292
$FEV_1\%(G)$ L	0.028	−0.190	89.313	0.527	6.147	−0.090	−0.249	111.052	0.514	7.441
V_{50} L/sec	0.043	−0.046	−0.385	0.701	1.146	0.014	−0.038	3.150	0.668	0.923
V_{25} L/sec	0.021	−0.031	−0.073	0.710	0.710	0.003	−0.025	2.155	0.736	0.474

血液ガス分圧

項目	男性(n=164)					女性(n=769)				
	a	b	定数	R	RSD	a	b	定数	R	RSD
Pao_2 TORR	0.084	0.014	70.489	0.070	7.461	−0.139	−0.152	114.690	0.206	9.276
$Paco_2$ TORR	0.012	0.032	41.344	0.157	3.751	0.029	0.014	35.382	0.049	3.879
HCO^3 mEq/L	0.015	0.000	22.340	0.062	1.890	−0.001	0.017	23.865	0.119	2.148
$AaDo_2$ TORR	0.099	0.024	29.695	0.138	7.518	0.104	0.135	−7.324	0.191	9.090

R：重相関係数　RSD：残差標準偏差

れば95%信頼限界を示す基準値であり，患者の呼吸機能検査成績を判別する際には，本人の様々な要因を加味して本基準値を用いるべきである．

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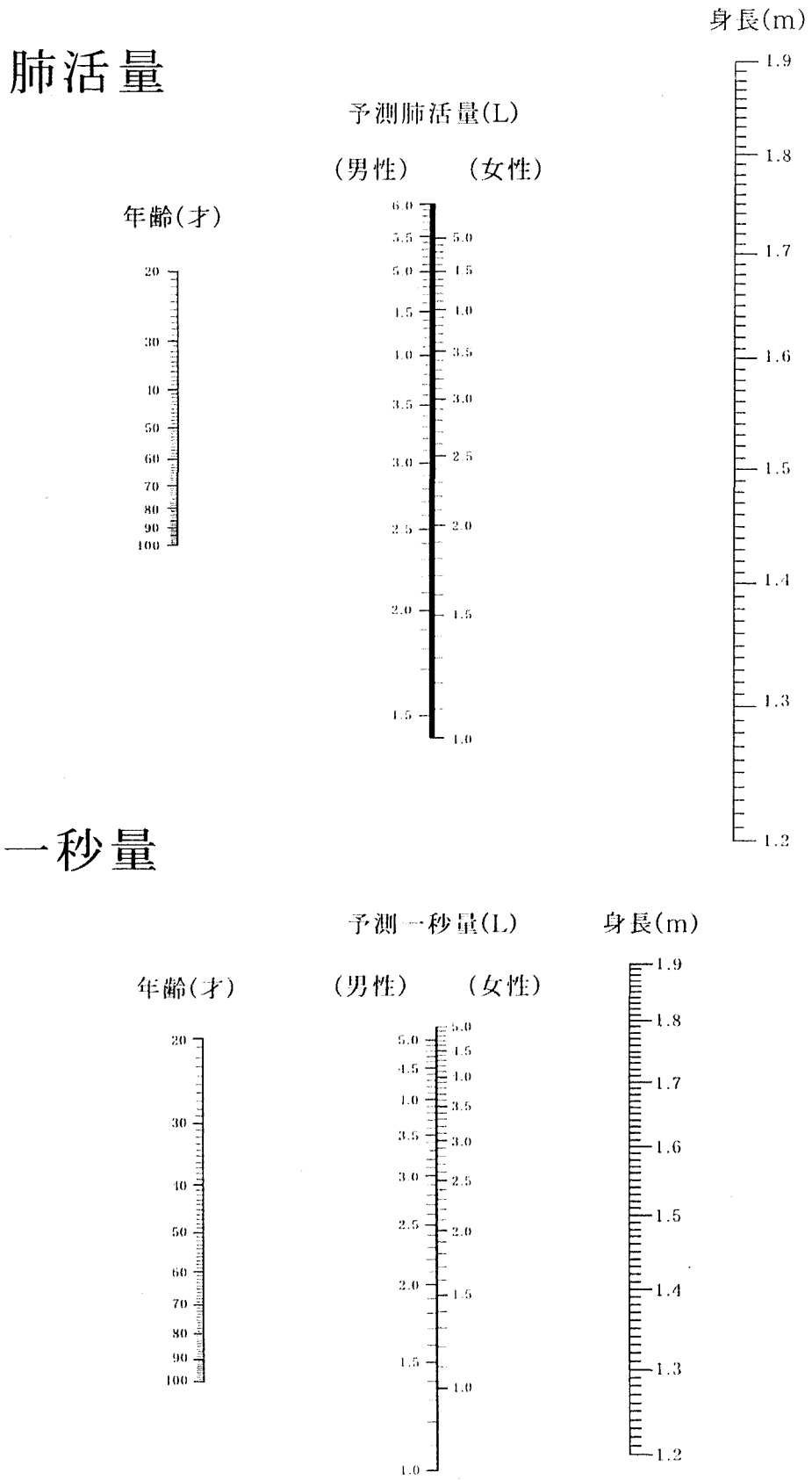

図 21 肺活量と一秒量のノモグラム

資料2－3

心肺同時移植希望者（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、この限りでない。

（3）肺の大きさ

肺の大きさは、臓器提供者（ドナー）及び移植希望者（レシピエント）の年齢区分に応じ、下記の方法で評価する。

1）臓器提供者（ドナー）及び移植希望者（レシピエント）がいずれも18歳以上の場合

（予測ＶＣＤ[注1]／予測ＶＣＲ[注2]－1）×100の値（%）で判断する。

① 片肺移植の場合 －30～30%

② 両肺移植の場合 －30～30%

注1） 予測ＶＣＤ：臓器提供者（ドナー）の予測肺活量

注2） 予測ＶＣＲ：移植希望者（レシピエント）の予測肺活量

予測肺活量の計算式

（男性） 予測肺活量（L）＝0.045×身長（cm）－0.023×年齢－2.258

（女性） 予測肺活量（L）＝0.032×身長（cm）－0.018×年齢－1.178

（日本呼吸器学会肺生理専門委員会 2001年4月）

2）臓器提供者（ドナー）及び移植希望者（レシピエント）がいずれも18歳未満の場合

（臓器提供者（ドナー）の身長／移植希望者（レシピエント）の身長－1）×100の値（%）で判断する。

① 片肺移植の場合 －12%～15%

② 両肺移植の場合 －12%～12%

3）臓器提供者（ドナー）及び移植希望者（レシピエント）の年齢が1）又は2）の場合に該当しない場合

（臓器提供者（ドナー）の身長／移植希望者（レシピエント）の身長－1）×100の値（%）で判断する。

① 片肺移植の場合 －12%～15%

② 両肺移植の場合 －12%～12%

（4）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。

（5）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。

（6）HLA型

当面、選択基準にしないが、必ず検査し、登録する。

（7）虚血許容時間

臓器提供者（ドナー）の心肺を摘出してから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が表示されていた場合には、当該親族を優先する。

（2）心臓移植希望者（レシピエント）選択基準で選ばれた移植希望者（レシピエント）が心肺同時移植の待機者である場合であって、かつ、臓器提供者（ドナー）から心臓及び両肺の提供があった場合には、当該待機者が肺移植待機リストで下位であっても、当該待機者に優先的に心臓及び両肺を同時に配分する。ただし、肺移植待機リストで選択された移植希望者（レシピエント）が優先すべき親族の場合はこの限りでない。

（3）肺移植希望者（レシピエント）選択基準で選ばれた移植希望者（レシピエント）が心肺同時移植の待機者である場合であって、かつ、臓器提供者（ドナー）から心臓及び両肺の提供があった場合には、当該待機者が心臓移植待機リストで下位であっても、当該待機者に優先的に心臓及び両肺を同時に配分する。ただし、心臓移植待機リストで選択された移植希望者（レシピエント）が優先すべき親族の場合はこの限りでない。

（4）心臓移植希望者（レシピエント）選択基準及び肺移植希望者（レシピエント）選択基準で選択された待機者が別人であり、共に心肺同時移植の待機者である場合であって、かつ、臓器提供者から心臓及び両肺の提供があった場合には、

① ＡＢＯ式血液型の一致(identical)する者を適合(compatible)する者より優先し、

② ①の条件が同一の移植希望者（レシピエント）が複数存在する場合は、心臓移植希望者（レシピエント）選択基準における医学的緊急度の高い者を優先し、

③ ①②の条件が同一の移植希望者（レシピエント）が複数存在する場合には、心臓移植希望者（レシピエント）選択基準の医学的緊急度 Status 1 の待機期間が長い者を優先し、

④ ①～③の条件が同一の移植希望者（レシピエント）が複数存在する場合には、登録日からの延べ日数の長い者を優先する。

（5）心臓又は肺の移植希望者（レシピエント）において、第1順位として選択された移植希望者（レシピエント）が心肺同時移植の待機者であっても、臓器提供者（ドナー）から心臓及び両肺の提供を受けられない場合は、心臓又は肺の単独移植希望者（レシピエント）のうちで最も優先順位が高いものを選択する。

3．その他

（1）臓器提供者（ドナー）又は移植希望者（レシピエント）が6歳以上18歳未満の場合、その予測肺活量については、以下の計算式を参考とすることができる。

予測肺活量の計算式（6歳以上18歳未満の場合）

（男性）予測肺活量（L）＝2.108－0.1262×年齢＋0.00819×年齢^2
－3.118×身長（m）＋2.553×身長（m）^{2}

（女性）予測肺活量（L）＝1.142－0.00168×年齢^2－2.374×身長（m）
＋2.116×身長（m）^{2}

（日本小児呼吸器疾患学会肺機能委員会 2008 年）

（2）医学的な理由により心臓移植希望者（レシピエント）選択基準における医学的緊急度が Status 3 になった場合、肺移植希望者（レシピエント）の待機リストを「待機 inactive」とする。

(附則)

1．心肺同時移植希望者（レシピエント）は、心臓移植希望者（レシピエント）のリスト及び肺移植希望者（レシピエント）のリストの両方に登録される。

2．心肺同時移植希望者（レシピエント）の心臓又は肺に係る待機期間については、既に心臓移植希望者（レシピエント）又は肺移植希望者（レシピエント）のリストに登録されている患者が術式を心肺同時移植に変更する場合には、心臓又は肺のうち、既に登録されているリストに係る待機日数は変更前の当該日数を含めて計算することとし、新規に登録されたリストに係る待機日数は新規に登録した以後の日数を計算することとする。

3．基準全般については、今後の移植医療の定着及び移植実績の評価等を踏まえ、適宜見直すこととする。

待機 inactive 制度について

1．概要

○　移植希望者（レシピエント）の容態が落ち着いており、当面の間、移植を受ける意思がない場合に、（社）日本臓器移植ネットワーク（以下「ネットワーク」という。）にその旨を事前に報告しておき、一時的に臓器あっせんの対象から除外する。

2．具体的な手順

○　患者と主治医との話し合いの結果、移植希望者（レシピエント）に当面の間移植を受ける意思がないことが確認された場合、各移植施設のネットワーク登録医師から、ネットワークへ書面により連絡する。

○　ネットワークは、移植施設に対して、当該移植希望者（レシピエント）を「待機 inactive 制度」の対象とした旨の連絡を行う。

○　また、移植希望者（レシピエント）が再度移植を希望した場合、各移植施設のネットワーク登録医師から、ネットワークへ書面により連絡する。

○　この場合についても、ネットワークは、移植施設に対して、当該移植希望者（レシピエント）を「待機 inactive 制度」の対象から外した旨の連絡を行う。

○　なお、「待機 inactive 制度」を利用している期間も、移植希望者（レシピエント）の待機期間の対象となる。

移植医療における今後の検討課題について（案）

移植医療のプロセス

医療機関

救急科や脳神経外科など
関係各科による診療

・入院患者　・ご家族

↓

脳死とされうる状態など
極めて重篤な状態

↓

提供の意思

↓

あっせん機関

・日本臓器移植ネットワーク
・各アイバンク
・コーディネーター
・広報活動

国及び
地方公共団体
関係団体

↓

移植施設

レシピエントの診療
メディカルコンサルタントの派遣など

・移植希望者　・ご家族

主な検討課題

Ⅰ　臓器提供施設への支援について

○臓器提供に係る手続きの負担軽減について
○体制整備に関する支援について

Ⅱ　ドナーファミリーのケアについて

○臓器提供に係る手続きの負担軽減について
○心のケアについて

Ⅲ　普及啓発等

○普及啓発の対象者と啓発方法について
○普及啓発の内容について

Ⅳ　コーディネーターの教育等について

○教育内容・体制について
○資質の向上・維持について

Ⅴ　移植の実施に係る課題について

○ドナー適応基準、レシピエント選択基準について
○検証のあり方について

資料3