資料１

腎臓移植希望者（レシピエント）選択基準について

１．経緯

平成７年に制定された腎臓移植希望者（レシピエント）選択基準については、阻血時間の短縮のため、都道府県内配分を中心とすること、及び小児患者並びに長期待機患者の優先度を上げることなどを考慮し、平成１４年１月に選択基準の改正を行った。

その後、平成２１年７月の「臓器の移植に関する法律の一部を改正する法律」の成立を踏まえ、平成２２年１月、選択基準における親族への優先提供に関する規定を定めた。

（改正の議論）

平成 13 年	2 月	第１回臓器移植委員会（腎臓移植の現状について議論）
	5 月	腎臓移植に関する作業班において議論（第１～５回）
	12 月	第５回臓器移植委員会（改正案について了承）
平成 14 年	1 月	選択基準の変更 ～新たな基準で運用
平成 21 年	11 月	第１回腎臓移植の基準等に関する作業班において議論
平成 22 年	1 月	選択基準の変更 ～新たな基準で運用

２．検討のポイント

（１）　第２回作業班（平成 22 年 8 月 26 日開催）で出された主な論点は以下のとおり。

１）　待機日数の長期化

平均待機日数：旧基準では 2,467 日、現行基準では 5,208 日

２）　16 歳以上の若年者への配分が少ない。

現行基準の運用開始以降提供された 1,327 例の腎移植の内、16 歳未満は約 6.63%（88 例）、16 歳から 20 歳未満はゼロ、20 歳代は 0.9%（12 例）

（2）　第3回作業班（平成22年10月25日開催）で出された主な論点は以下のとおり

- 16歳になると急に加点がゼロになるのは問題ではないか。登録時16歳未満でも移植を受けずに16歳以上になる患者もいる。

- 小児については最優先に移植するようにすべき

- 待機患者の年齢構成も考慮すべき。あまり大きな変更は長期待機患者の期待に反することになる。

- 提供数が限られている現状では、とりあえずマイナーチェンジにとどめ、例えば3年後に見直してはどうか。

- Flow cytometry等の「等」について明示すべき。

- 英国などではPRA検査陽性患者についてはHLA適合度が高い場合には優先させるという取り扱いもある、陽性の場合にはネグレクトという基準は良くない。

資料２

腎臓移植希望者（レシピエント）選択基準改訂に係る再シミュレーションの状況

前回（10 月 25 日開催）の班会議における議論を踏まえ、次の観点からシミュレーションを行った。
＊16 歳～20 歳未満の加点により、この年齢層の候補者がどのように変化するか。
＊各年齢層への加点を加減することにより、長期待機患者等へのどのような影響が認められるか。

1 シミュレーションの前提条件

＊ ドナー条件：現行基準で行われた脳死下での提供事例 33 例（関東甲信越ブロック発生症例）
＊ 待機患者条件：平成 22 年 10 月 13 日現在の待機患者 4567 名（関東甲信越地方のみ）

2 シミュレーションの方法

下記の条件ごとに、レシピエント候補者を選択し第 1 位及び第 2 位につき、検討した。（N=66）
若年者への加点は 20 歳を上限とした。

A：現行基準
B：待機期間の配点は現行基準：HLA×1.15※1　16 歳未満：14 点、16 歳～20 歳未満：12 点
C：待機日数の配点を概ね半減し※2、年齢加点を、
「16 歳未満：10 点、16 歳～20 歳未満：6 点」とする。

※1 現行基準で行われた脳死下での腎提供事例 80 例について、レシピエント選択リストを作成し、そのリストの第 1 位のレシピエント 80 名の所在地、HLA、待機日数の平均換算点数の比は概ね 1.15：1：1.15 である。

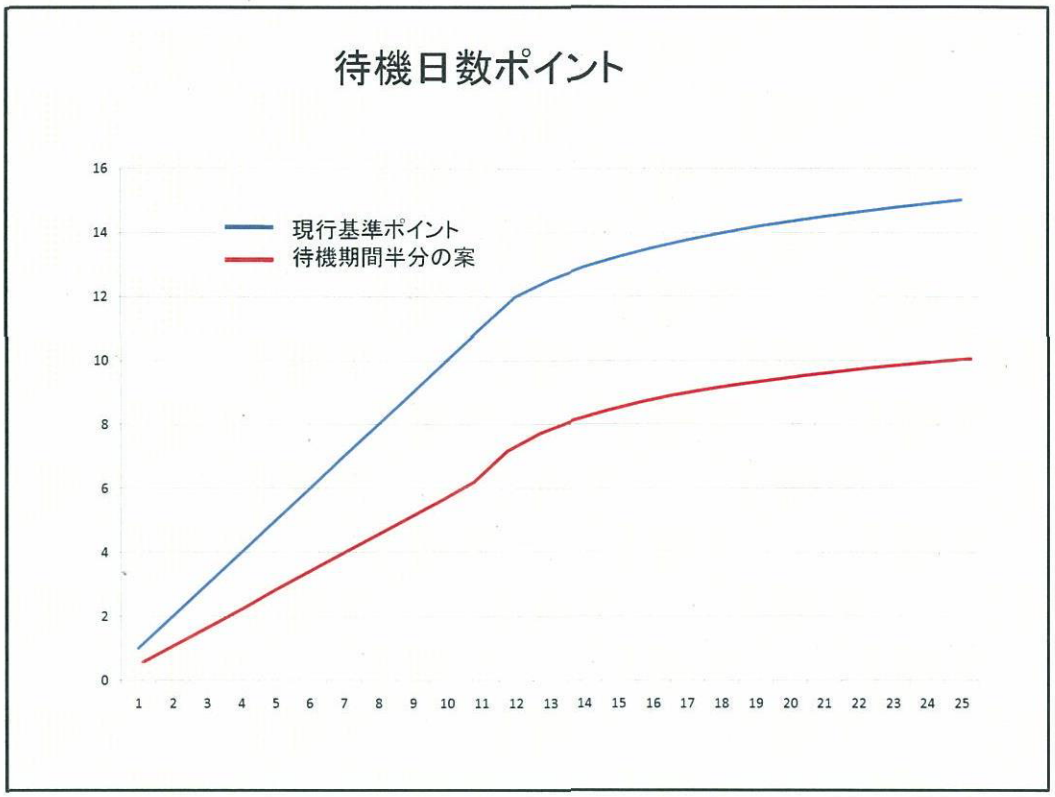
※2 待機期間が 10 年までは 0.5 点／年、11 年～20 年までは 0.25 点／年、20 年以上は 0.125 点／年となるような近似値を log 式とする。（別紙参照）

3 シミュレーション結果

		A（現行基準）	B	C
レシピエント候補者の平均待機日数	全体	5289.4 日	5281.45 日	4274.7 日
	16 歳未満	997.25 日	937.08 日	1041.38 日
	16 歳～20 歳未満	―	983 日	983 日
	20 歳以上	6663 日	6496.04 日	6006.86 日
レシピエント候補者の人数（%）	16 歳未満	16 人（24.2）	13 人（19.7）	21 人（31.8）
	16 歳～20 歳未満	0 人（0）	2 人（3）	2 人（3）
	20 歳以上待機期間 10 年未満	1 人（1.5）	2 人（3）	4 人（6.1）
	その他	49 人（74.3）	49 人（74.2）	39 人（59.1）

%はレシピエント候補者 66 名に対するもの

別紙


待機日数ポイント
現行基準ポイント
待機期間半分の案
0
2
4
6
8
10
12
14
16
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

資料３

腎臓移植希望者（レシピエント）選択基準（案）

１．前提条件

（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）リンパ球直接交叉試験（全リンパ球又はＴリンパ球）陰性

なお、リンパ球交叉試験はFlow cytometry又はこれに準ずる高感度方法を用いて行うことが望ましい。

２．優先順位

（１）搬送時間（阻血時間）

地　域	点　数
同一都道府県内（注）	１２点
同一ブロック内	６点

＊　移植希望者の登録地域は移植希望施設の所在地（都道府県）とする。

（２）ＨＬＡの適合度

ＤＲ座の適合（ミスマッチ数）	Ａ座及びＢ座の適合（ミスマッチ数）	点　数
0	0	１４
0	1	１３
0	2	１２
0	3	１１
0	4	１０
1	0	９
1	1	８
1	2	７
1	3	６
1	4	５
2	0	４
2	1	３
2	2	２
2	3	１
2	4	０点

×１．１５点

（3）待機日数

待機日数（N）≦4014 日：待機日数ポイント＝N/365 点

待機日数（N）＞4014 日：待機日数ポイント＝10＋log1.74（N/365－9）点

（4）~~小児待機患者~~ 未成年者

１６歳未満については１４点を加算する。

１６歳～２０歳未満については１２点加点する。

３．具体的選択法

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）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式血液型が一致（identical）する者を適合（compatible）する者より優先する。

（3）２．の（1）～（4）の合計点数が高い順とする。ただし、これらの条件が同一の移植希望者（レシピエント）が複数存在した場合には、臓器搬送に要する時間、医学的条件に配慮する。

また、ＰＲＡ検査が可能な場合、ＰＲＡ検査陰性を満たすこと~~とする~~が望ましい。

（注１）地域は、原則として、都道府県、ブロック内他都道府県とする。ただし、地域の実情を踏まえ、（社）日本臓器移植ネットワークにおいて複数の都道府県を統合したサブブロックを設置することも可能とする。

（注２）１年以内に移植希望者（レシピエント）の登録情報が更新されていることを必要条件とする。

（注３）Ｃ型肝炎抗体陽性ドナーからの移植は、Ｃ型肝炎抗体陽性レシピエントのみを対象とするが、リスクについては十分に説明し承諾を得られた場合にのみ移植可能とする。

（注４）~~新ルールの下での状況について、実施後１年のデータが蓄積された時点で新ルールを検討するが、必要があれば追加すべき事項について検討する。~~

新ルール実施後１年を目途に新ルールの状況について検討を行うとともに、今後新たな医学的知見を踏まえ、PRA 検査の取り扱い等について適宜検討を行い、必要があれば、基準の見直しを行うこととする。

参考資料１

第３回腎臓移植の基準等に
関する作業班（H22.10.25）
資料 1-2

腎臓移植希望者（レシピエント）選択基準改訂に係るシミュレーションの結果

１　シミュレーションの前提条件

＊　ドナー条件：現行基準で行われた脳死下での提供事例 30 例

＊　待機患者条件：平成 22 年 10 月 13 日現在の待機患者 11,708 名

２　シミュレーションの方法

下記の条件ごとに、レシピエント候補者を選択し第１位及び第２位につき、検討した。結果については別紙参照。

A　：現行基準

B　：現行基準から、HLA の点数を 1.15 倍※1 とした。

C-1：待機日数の配点を概ね半減し※2、小児の年齢加点を 0 とする。

C-2：待機日数の配点を概ね半減し※2、年齢加点を、
「16 歳未満：8 点、16 歳～20 歳未満：4 点、20 歳代：2 点」とする。

C-3：待機日数の配点を概ね半減し※2、年齢加点を、
「16 歳未満：12 点、16 歳～20 歳未満：6 点、20 歳代：3 点」とする。

※1　現行基準で行われた脳死下での腎提供事例 80 例について、レシピエント選択リストを作成し、そのリストの第１位のレシピエント 80 名の所在地、HLA、待機日数の平均換算点数の比は概ね 1.15：1：1.15 である。

※2　待機期間が 10 年までは 0.5 点／年、11 年～20 年までは 0.25 点／年、20 年以上は 0.125 点／年となるような近似値を log 式とする。

３　現行基準の分析

レシピエント選択時における患者本人の意思確認等の影響を除去するため、過去 80 例（脳死提供事例 20～102 例目まで：腎選定が行われなかったものを除く）の提供事例において、第１位にリストアップされた患者の分析を行った。

提供事例 80 例の実際の第一位患者 80 名

平均点　　：所在地：11.4 点　　HLA：9.98 点　　待機期間：11.49 点

平均待機日数：5412.1 日

16 歳未満が第一位：16 名（20%）

別紙

シミュレーションの結果概要

	A	B	C-1	C-2	C-3	実績＊	3の分析
平均待機日数(日)	5,579.1	5,610.4	5,091	4,718.1	3,529.1	5,207.9	5,412.1
うち16歳以上(日)	6,357.3	6,309	5,091	4,883.2	4,767	5,521	6,389.7
16歳未満　人(%)	9 (15)	8 (13)	0	3 (5)	20 (33)	88 (8)	16 (20)
16歳から20歳未満	0	0	0	0	1(2)	0	0
20歳台	0	0	0	8 (13)	8 (13)	12 (0.9)	1 (1.3)
待機期間10年未満、16歳以上の候補者数　人(%)	0	3 (5)	7 (12)	5 (8)	14 (15)		3(3.7)

＊実績は参考資料1を参照

A,B,C:n=60　3の分析:n＝80　実績:n=1,327

参考資料２

腎臓移植希望者（レシピエント）待機者の状況

１．　全国の腎臓移植希望待機患者の分布

年代	待機患者数（人）	%
0-15	50	0.43%
16-19	32	0.27%
20 代	343	2.93%
30 代	1,539	13.14%
40 代	3,248	27.74%
50 代	3,971	33.92%
60 代	2,312	19.75%
70 以上	213	1.82%
	11,708	

平成 22 年 9 月 30 日現在

２．　16 歳未満で登録した患者の現在の年齢分布

	現在の年齢		
登録時年齢	0-15	16-19	20-
0-5	16 人		
6-10	15 人	1 人	10 人
11-15	19 人	14 人	57 人
総計	50 人	15 人	67 人

平成 22 年 11 月 10 日現在

参考資料３

腎臓移植希望者(レシピエント)選択基準の運用状況について
(社団法人日本臓器移植ネットワーク提出資料)

レシピエント選択基準変更前後のシッピング

旧基準　(1995.4.1 ～ 2002.1.9　N=1,063)
新基準　(2002.1.10～2009.12.31　N=1,327)

	同一県内	ブロック内県外	ブロック外	小児
旧基準	29.0 %	58.9%	12.1 %	2.7 %
新基準	81.5 %	18.3%	0.2%	6.6%

レシピエント選択基準変更前後の HLA不適合抗原数・ドナー年齢・阻血時間

旧基準　(1995.4.1 ～ 2002.1.9　N=1,063)
新基準　(2002.1.10～2009.12.31　N=1,327)

	HLA不適合抗原数(検索型)		ドナー年齢	温阻血時間	総阻血時間
	DR	AB		(分)	(分)
旧基準	0.11 ± 0.34	1.28 ± 0.98	45.44 ± 17.11	7.94 ± 10.85	861.09 ± 402.95
新基準	0.51 ± 0.54	2.17 ± 0.97	48.94 ± 15.65	7.19 ± 8.97	731.01 ± 359.00
	(P<.001)	(P<.001)	(P<.001)		(P<.001)

レシピエント選択基準変更前後の
レシピエント年齢・待機期間・透析期間

旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

	レシピエント年齢（全体）	レシピエント年齢（16歳以上）	待機期間（年）	透析期間（年）
旧基準	44.60 ± 11.22	45.56 ± 9.80	6.76 ± 4.86	10.12 ± 6.21
新基準	47.44 ± 12.88	50.05 ± 8.58	14.27 ± 5.37	17.24 ± 6.70
	(P<.001)	(P<.001)	(P<.001)	(P<.001)

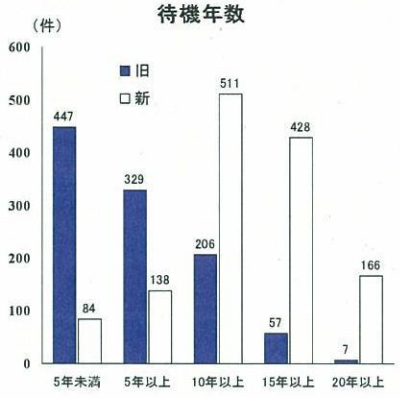
レシピエント選択基準変更前後の
レシピエント待機日数・透析日数

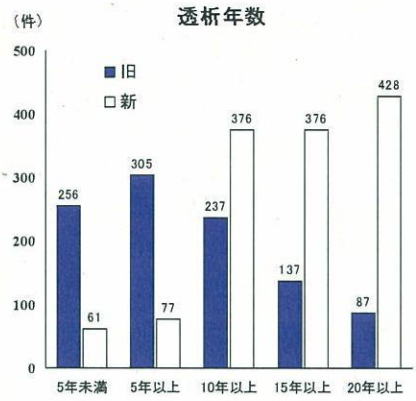
旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

		待機日数	透析日数	
旧基準		2467.04±1772.57	3694.26±2265.90	(P<.001)
新基準	全体	5207.99±1958.52	6292.61±2446.02	
	16歳以上	5521.06±1610.10	6631.28±2141.61	(P<.001)
	16歳未満	800.19±724.71	1489.00±1042.23	

選択基準変更前後の待機年数および透析年数
（腎単独移植のみ）

旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）





レシピエント選択基準変更前後の生存率・生着率

旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

生存率（%）

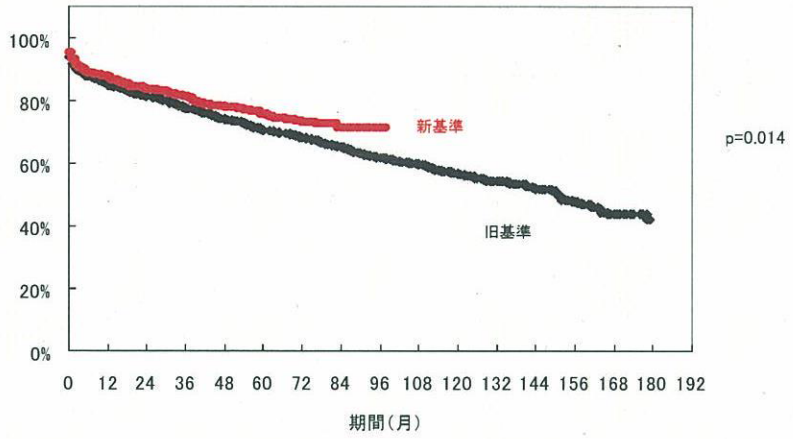
	1カ月	1年	3年	5年	(Logrank)
旧基準	98.2	95.3	91.5	89.3	p=0.135
新基準	98.0	96.1	93.7	91.7	

生着率（%）

	1カ月	1年	3年	5年	(Logrank)
旧基準	91.7	84.9	77.5	70.5	p=0.014
新基準	93.1	87.5	81.2	75.6	

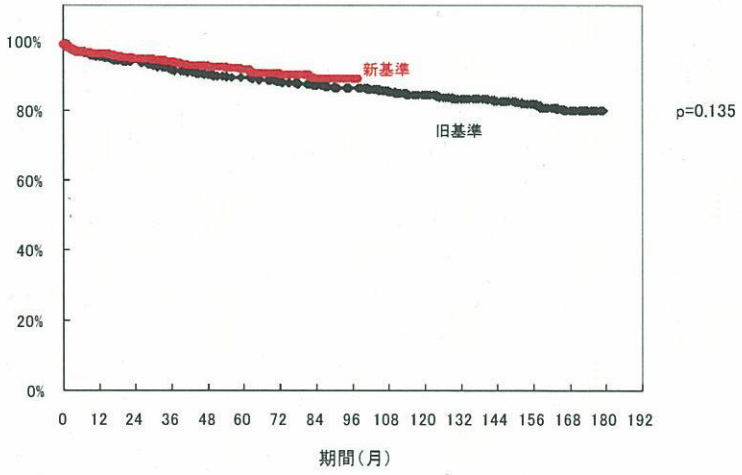
生着率　選択基準別

旧基準　（1995.4.1 ～2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

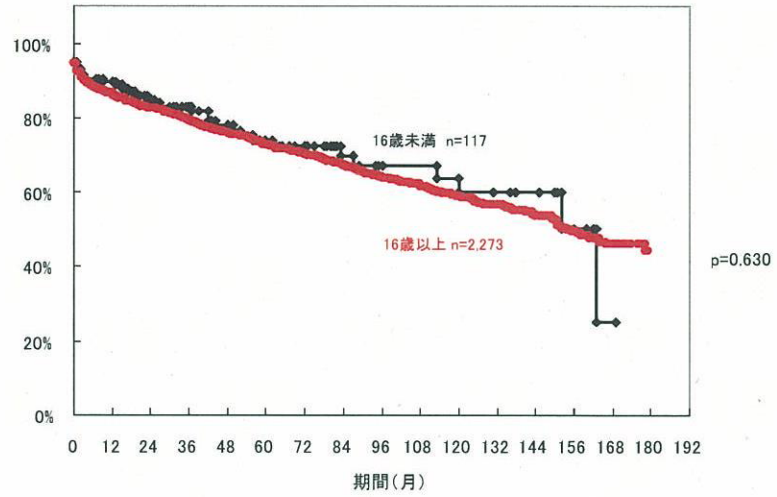


生存率　選択基準別

旧基準　（1995.4.1 ～2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）



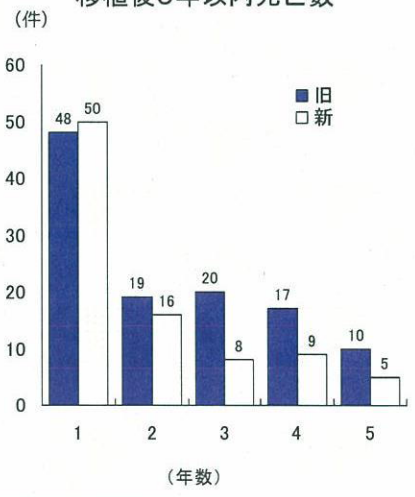
生着率　16歳未満・以上
（1995.4.1～2009.12.31）



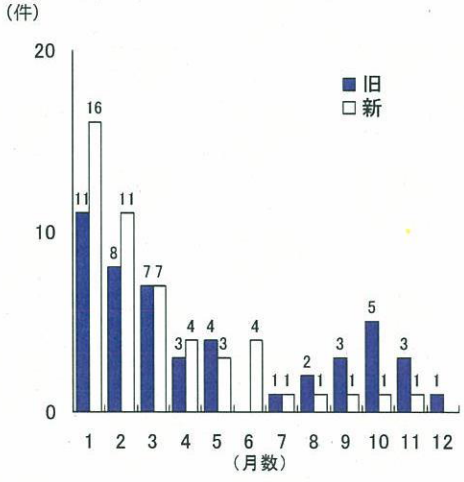
レシピエント選択基準変更前後の移植後死亡数

旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

移植後5年以内死亡数



移植後1年以内死亡数



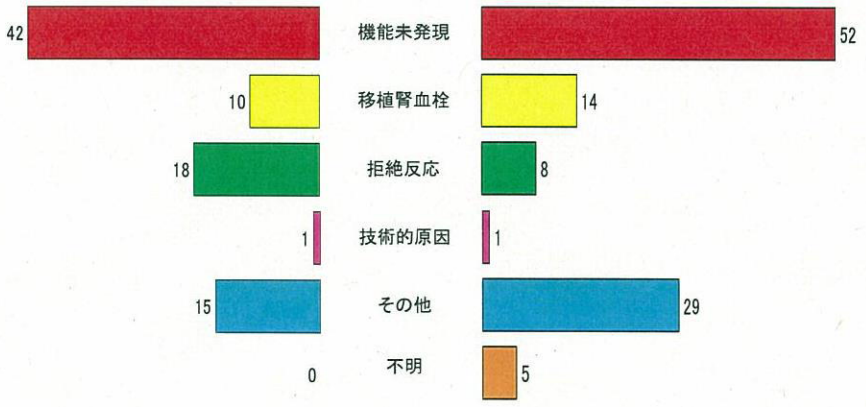
レシピエント選択基準変更前後の移植後無機能腎・術後透析期間・死亡・生着率

旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

	離脱不能（%）	機能未発現（%）	術後透析期間（日）	移植後死亡(%) 3カ月	6カ月	12カ月
旧基準	8.1	4.0	15.07±63.81	2.7	3.2	4.7
新基準	8.2	3.9	12.92±19.71	2.6	3.4	3.8

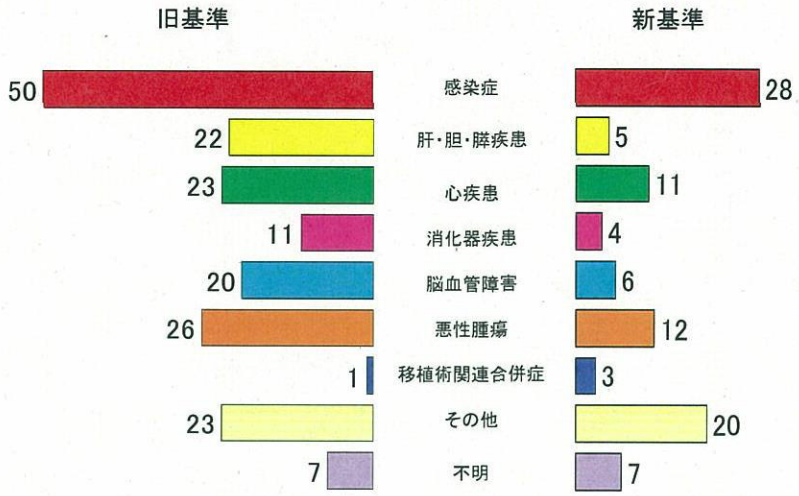
透析離脱不能例とその原因

旧基準		新基準
86/1063 (8.1%)	透析離脱不能例	109/1327(8.2%)
42/1063 (4.0%)	機能未発現	52/1327 (3.9%)

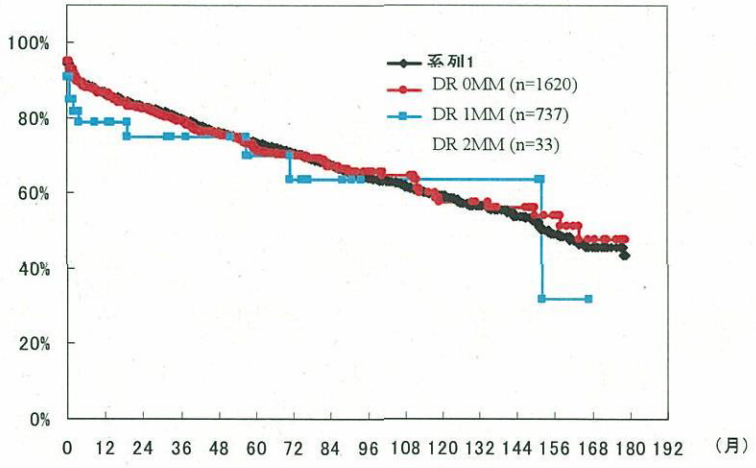


レシピエント選択基準変更前後の移植後死因

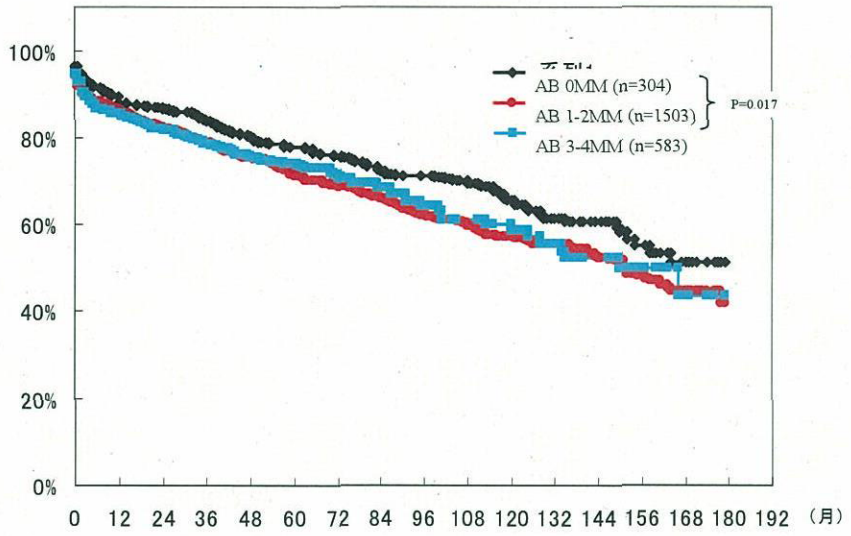
旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）



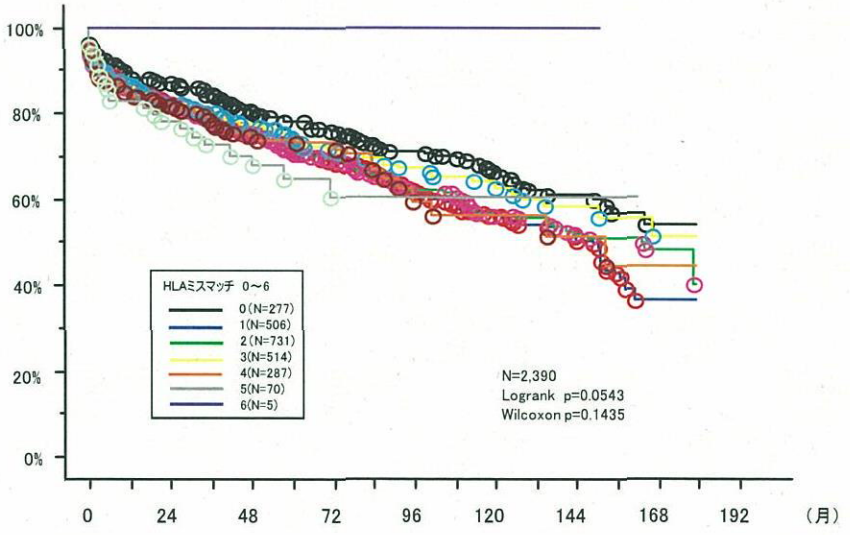
HLA不適合抗原数(検索型DR) 生着率



HLA不適合抗原数(検索型A･B) 生着率



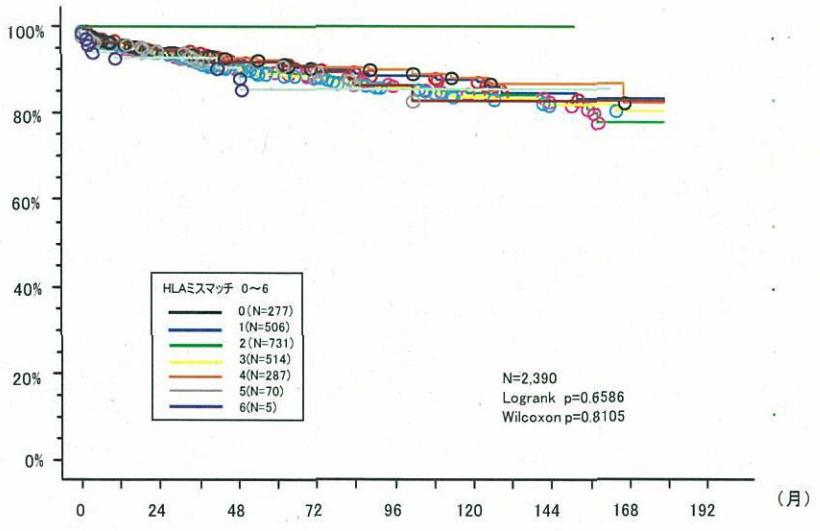
HLA不適合抗原数(検索型A･B･DR) 生着率



HLA不適合抗原数(検索型A・B・DR) 生着率

ミスマッチ数	1年	2年	3年	4年	5年	6年	7年	8年	9年	10年
0	88.4%	87.0%	84.4%	80.2%	77.9%	75.5%	72.3%	71.1%	69.4%	66.3%
1	86.1%	82.3%	78.5%	74.6%	71.5%	68.3%	66.3%	61.6%	58.4%	56.3%
2	86.0%	81.8%	78.6%	75.5%	70.8%	68.9%	65.3%	62.0%	60.5%	56.4%
3	86.9%	82.4%	80.2%	77.4%	74.0%	71.4%	69.7%	67.3%	65.2%	62.7%
4	85.3%	81.6%	77.8%	74.6%	73.9%	71.8%	66.9%	59.6%	55.9%	55.9%
5	82.8%	78.0%	72.5%	67.7%	64.9%	60.3%	60.3%	60.3%	60.3%	60.3%
6	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

HLA不適合抗原数(検索型A・B・DR) 生存率

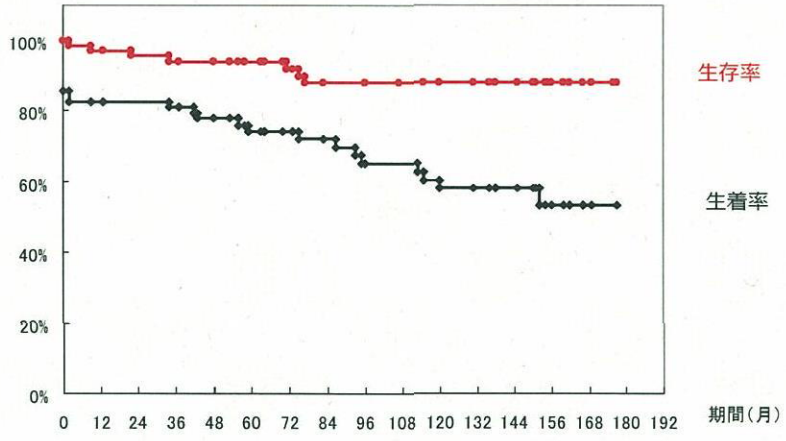


HLA不適合抗原数(検索型A・B・DR) 生存率

ミスマッチ数	1年	2年	3年	4年	5年	6年	7年	8年	9年	10年
0	96.0%	94.9%	94.2%	92.3%	91.5%	89.9%	89.1%	88.7%	88.3%	87.8%
1	95.2%	94.2%	91.7%	90.5%	89.8%	88.4%	87.6%	86.4%	85.5%	84.8%
2	95.7%	93.9%	91.9%	90.4%	89.0%	88.3%	86.7%	85.8%	84.8%	83.7%
3	96.3%	94.5%	93.7%	92.8%	92.4%	90.7%	90.7%	90.0%	89.1%	88.1%
4	96.2%	94.5%	92.3%	91.7%	91.7%	89.7%	86.2%	86.2%	82.8%	82.8%
5	92.8%	92.8%	92.8%	88.0%	85.5%	85.5%	85.5%	85.5%	85.5%	85.5%
6	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

小児提供者(16歳未満)からの(心臓停止後腎臓提供) 腎臓移植 生存・生着

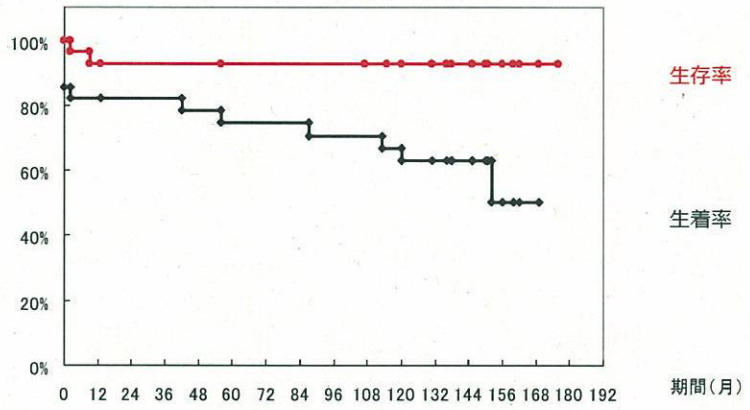
(1995.4-2009.12 N=69)



	1カ月	1年	3年	5年	10年
生存率	100%	98.6%	97.1%	94.0%	87.9%
生着率	85.5%	82.6%	81.1%	74.1%	60.4%

小児提供者(16歳未満)から小児(16歳未満)への(心臓停止後腎臓提供)腎臓移植　生存・生着

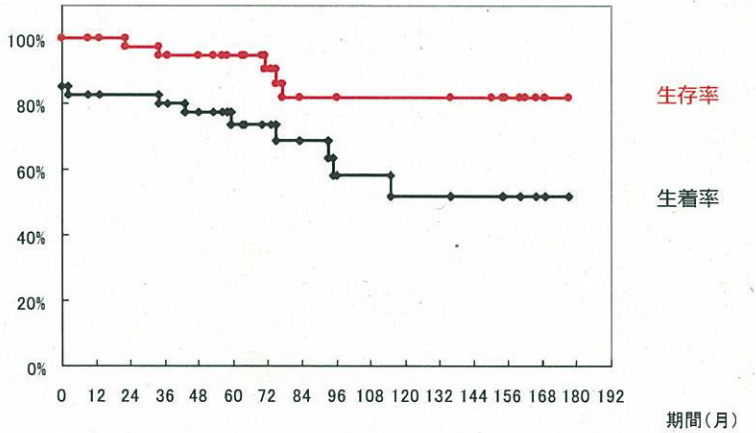
(1995.4-2009.12　N=28)



	1カ月	1年	3年	5年	10年
生存率	100%	92.9%	92.9%	92.9%	92.9%
生着率	85.7%	82.1%	82.1%	74.7%	66.8%

小児提供者(16歳未満)から16歳以上への(心臓停止後腎臓提供)腎臓移植　生存・生着

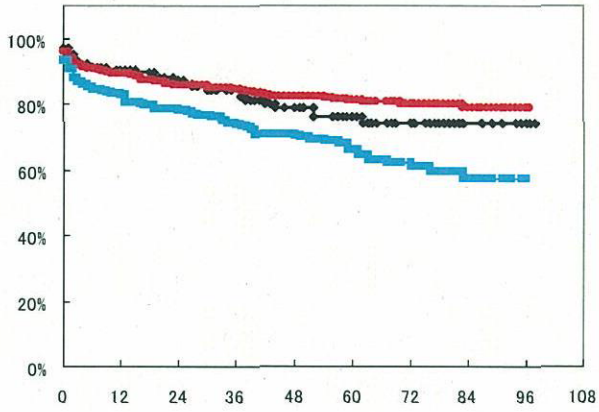
(1995.4-2009.12　N=41)



	1カ月	1年	3年	5年	10年
生存率	100%	100%	94.7%	94.7%	82.0%
生着率	82.9%	82.9%	80.3%	73.7%	51.7%

新基準による腎臓移植　生着率×透析期間

（透析導入日不明のデータを除く）



透析10年以上 n=741

透析10年未満 n=149

透析20年以上 n=426

	1カ月	1年	3年	5年
10年未満	95.3%	90.5%	84.5%	76.0%
10年以上	94.1%	89.5%	84.9%	81.2%
20年以上	90.4%	83.0%	74.2%	65.9%

p<0.01

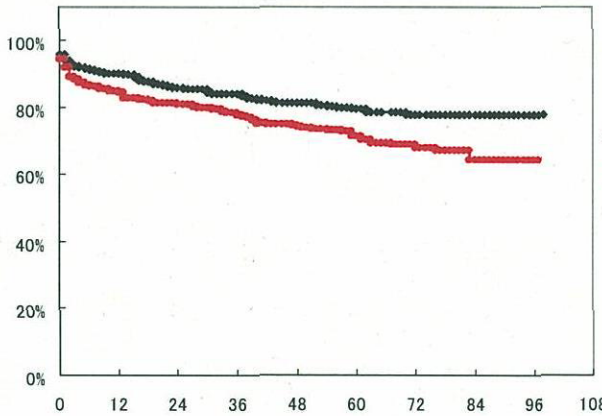
p<0.01

新基準による腎臓移植　生着率×透析期間

（透析導入日不明のデータを除く）

移植までの平均透析期間の17年で区別

p<0.01



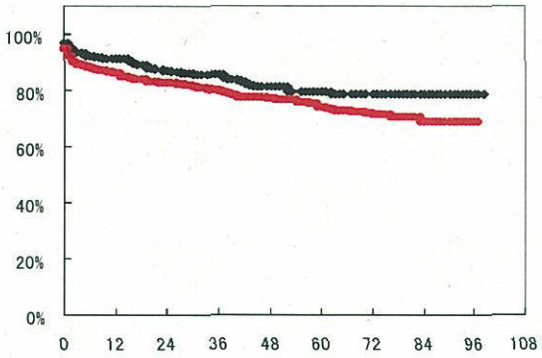
透析17年未満　n=682

透析17年以上 n=634

	1月	1年	3年	5年
17年未満	94.1%	90.1%	84.1%	79.5%
17年以上	91.8%	84.8%	78.4%	71.4%

新基準による腎臓移植　生着率×透析期間

（透析導入日不明のデータを除く）



P=0.02

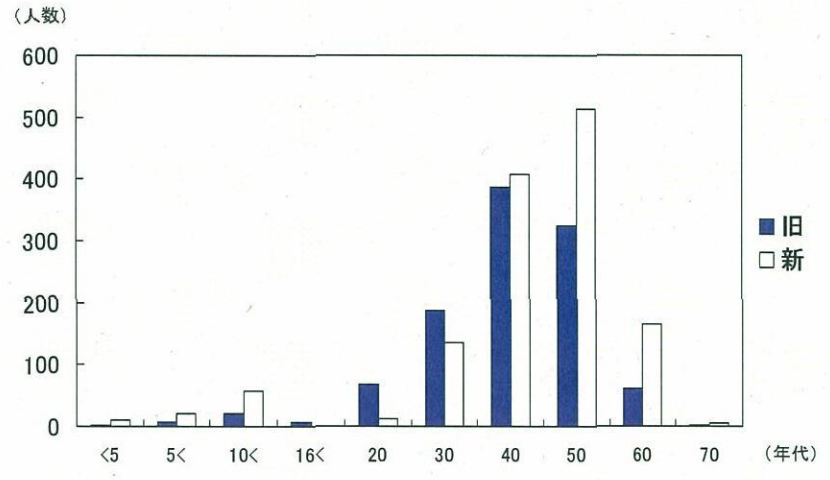
透析13年未満　n=340

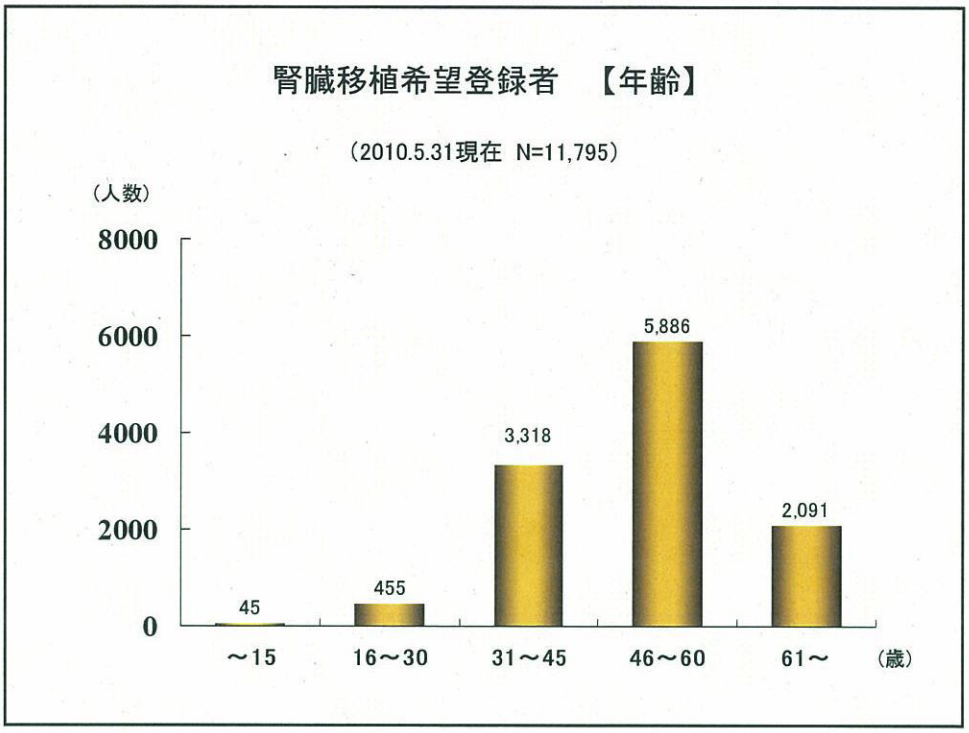
透析13年以上 n=976

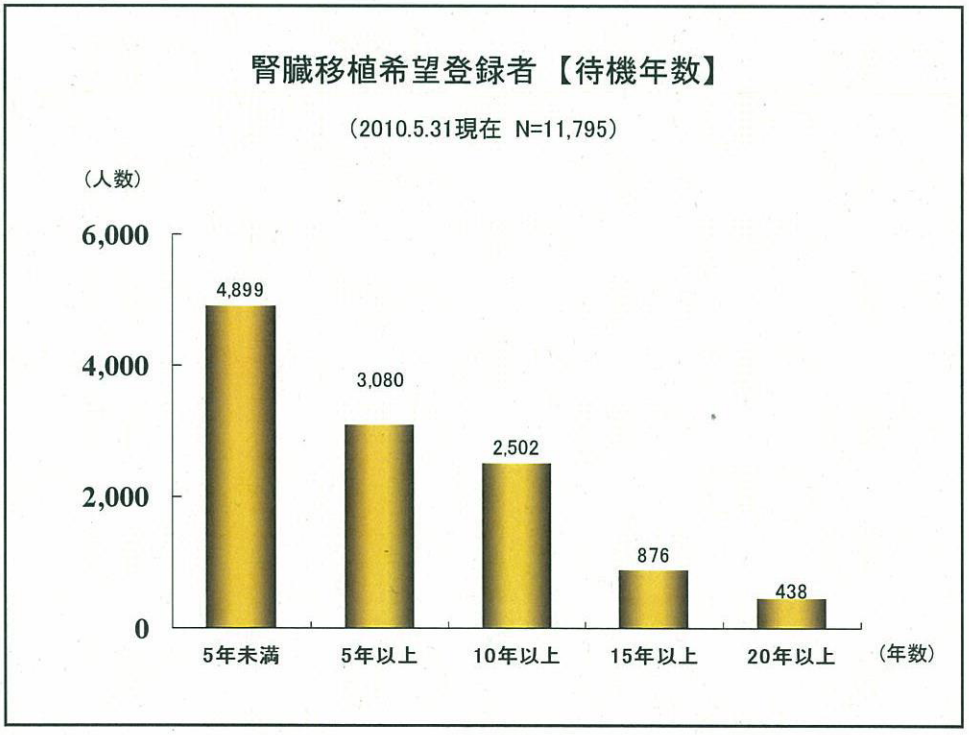
	1月	1年	3年	5年
13年未満	95.3%	91.1%	85.5%	79.8%
13年以上	92.2%	86.1%	79.5%	74.1%

配分基準・年代別移植者数

旧基準　（1995.4.1 ～ 2002.1.9　N=1,063）
新基準　（2002.1.10～2009.12.31　N=1,327）

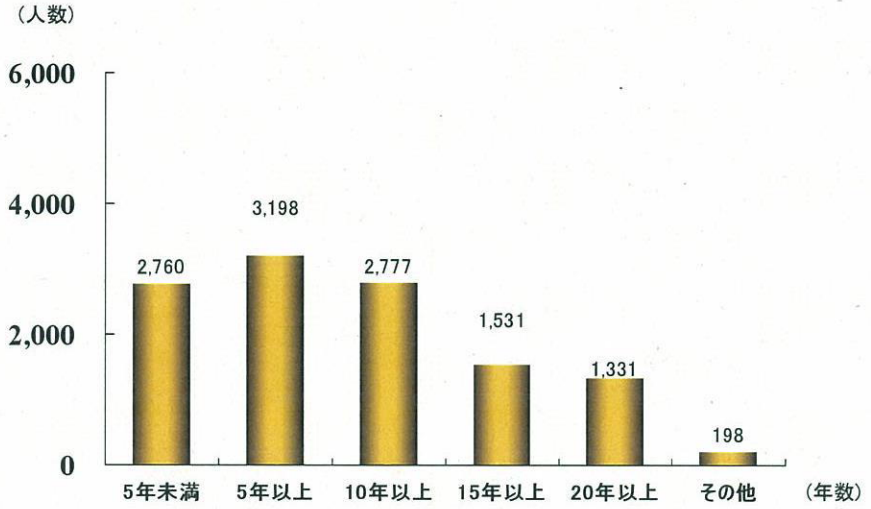



腎臓移植希望登録者　【年齢】
(2010.5.31現在 N=11,795)
(人数)
8000
6000
4000
2000
0
45
455
3,318
5,886
2,091
～15
16～30
31～45
46～60
61～
(歳)


腎臓移植希望登録者【待機年数】
(2010.5.31現在 N=11,795)
(人数)
6,000
4,000
2,000
0
4,899
3,080
2,502
876
438
5年未満
5年以上
10年以上
15年以上
20年以上
(年数)

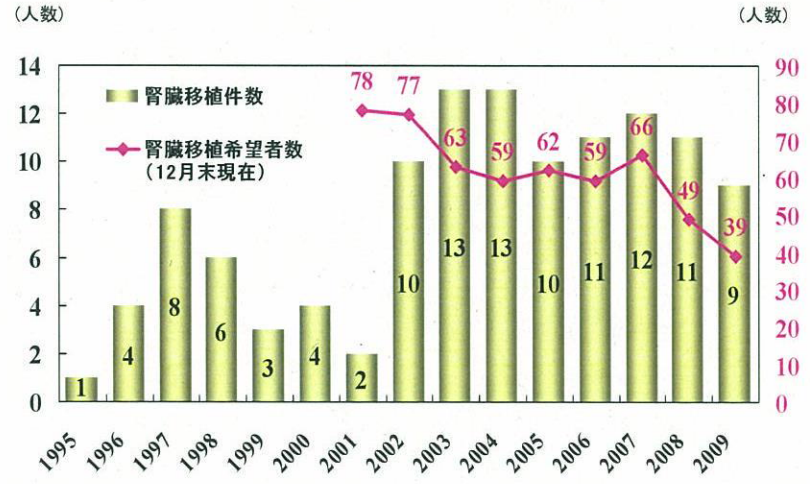
腎臓移植希望登録者【透析年数】

（2010.5.31現在 N=11,795）



小児腎臓移植件数・腎臓移植希望者数の推移

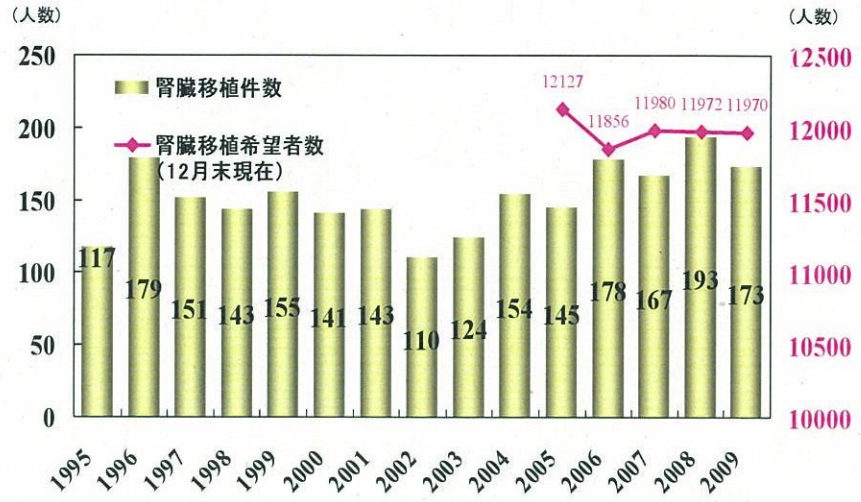
（16歳未満 1995年4月～2009年12月）



＊2002年1月10日より腎臓移植レシピエント選択基準が改正され、小児への移植が優先されるようになった

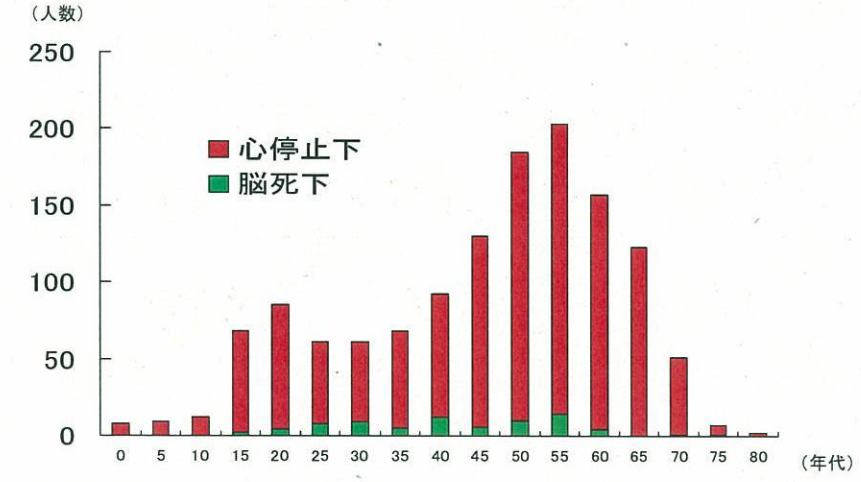
腎臓移植件数・腎臓移植希望者数の推移

（16歳以上　1995年4月～2009年12月）



腎臓提供者 【年代】

（1995/4～2009/12　脳死下N=76　心停止下N=1246）



参考資料４

腎臓移植希望者（レシピエント）選択基準

１．前提条件

（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）リンパ球直接交叉試験（全リンパ球又はＴリンパ球）陰性

２．優先順位

（１）搬送時間（阻血時間）

地　域	点　数
同一都道府県内（注）	１２点
同一ブロック内	６点

＊　移植希望者の登録地域は移植希望施設の所在地（都道府県）とする。

（２）ＨＬＡの適合度

ＤＲ座の適合数 （ミスマッチ数）	Ａ座及びＢ座の適合数 （ミスマッチ数）	点　数
0	0	１４点
0	1	１３点
0	2	１２点
0	3	１１点
0	4	１０点
1	0	９点
1	1	８点
1	2	７点
1	3	６点
1	4	５点
2	0	４点
2	1	３点
2	2	２点
2	3	１点
2	4	０点

（3）待機日数

待機日数（N）≦4014 日：待機日数ポイント＝N/365 点

待機日数（N）＞4014 日：待機日数ポイント＝10＋log1.74（N/365－9）点

（4）小児待機患者

小児待機患者（１６歳未満）については１４点を加算する。

3．具体的選択法

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）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式血液型が一致（identical）する者を適合（compatible）する者より優先する。

（3）２．の（1）～（4）の合計点数が高い順とする。ただし、これらの条件が同一の移植希望者（レシピエント）が複数存在した場合には、臓器搬送に要する時間、医学的条件に配慮する。

また、ＰＲＡ検査が可能な場合はＰＲＡ検査陰性を満たすこととする。

（注１）地域は、原則として、都道府県、ブロック内他都道府県とする。ただし、地域の実情を踏まえ、（社）日本臓器移植ネットワークにおいて複数の都道府県を統合したサブブロックを設置することも可能とする。

（注２）１年以内に移植希望者（レシピエント）の登録情報が更新されていることを必要条件とする。

（注３）Ｃ型肝炎抗体陽性ドナーからの移植は、Ｃ型肝炎抗体陽性レシピエントのみを対象とするが、リスクについては十分に説明し承諾を得られた場合にのみ移植可能とする。

（注４）新ルールの下での状況について、実施後１年のデータが蓄積された時点で新ルールを検討するが、必要があれば追加すべき事項について検討する。

参考資料5

日本移植学会・日本組織適合性学会　共同作業部会

HLA に関わる選択基準（提言）

（1）現在、腎臓移植の基準等に関する作業班にて「腎移植希望者（レシピエント）選択基準について」改正のため審議中であり、腎移植配分ルールの見直し作業が行われている。 専門領域に携わる日本移植学会、日本組織適合性学会の共同作業部会名にて HLA に関わる選択基準の提言を下記のように行うこととした。

1. 前提条件 （2）リンパ球直接交叉試験（全リンパ球又は T リンパ球）陰性
（修正案）
高感度のリンパ球交叉試験陰性
（解説） 最近は、高感度のリンパ球交叉試験方法が開発されている。とくに Flow cytometry などを用いる方法が該当する。 直接試験とは、もともと交叉試験方法におけるリンパ球に二次抗体を利用しない方法であり、AHG、Flow cytometry は、間接試験と分類される。

3. 具体的選択法 （3） ――また、PRA 検査が可能な場合には、PRA 検査陰性を満たすこととする
（修正案）移植希望者の PRA 検査（HLA 抗体スクリーニング）は、高感度方法を用いて実施することが望ましい。
（解説）PRA 陽性、クロスマッチ陰性は、海外では移植のよい適応となっている。海外では、バーチャルクロスマッチの導入を試みているところもある。候補者の HLA 抗体保有データは、移植レシピエント選択に有用な情報を提供する。

（修正案：下記を追加）
（注5） HLA 検査施設が提供する具体的な検査内容については、関連学会（日本組織適合性学会および日本移植学会）委員会により作成したガイドラインに準拠する。

（2）ドナー発生時における Flow cytometry クロスマッチの緊急対応が可能な施設について話し合った。人員、予算、設備機器不足問題を解決しなければならないが、現在のところ、東北地方では、福島県立医大のみ Flow cytometry が設置されている。東京では、少なくとも 3 施設は必要であると考えられる。

（3）HLA タイピングは、現在、2 桁対応であるが、4 桁は不要である。

参考資料6

3.5 ALLOCATION OF DECEASED KIDNEYS. Deceased kidneys must be allocated according to the following policies. The final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of the candidate. This allows physicians and surgeons to exercise their medical judgment regarding the suitability of the organ being offered for a specific candidate; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia time and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If an organ is declined for a candidate, a notation of the reason for that decision must be made on the appropriate form and submitted promptly.

3.5.1 Definition of Expanded Criteria Donor and Standard Donor. For purposes of Policy 3.5 (Allocation of Deceased Kidneys), expanded criteria donors are defined by an "X" in the decision matrix shown below indicating relative risk of graft failure for donors older than 10 years of age > 1.7, based upon the following factors: age, creatinine, CVA, and hypertension. Standard donors are all other donors. Unless specified as an expanded criteria donor or standard donor, the term donor(s) means all donors, expanded and standard. For purposes of distinguishing expanded criteria donors from standard donors, the most recent creatinine at the time of kidney placement shall be used.

Candidates who agree to receive expanded criteria donor kidneys shall be eligible also to receive standard donor kidneys according to the policies described below for allocating standard donor kidneys. The program shall obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation.

Donor Condition	**Donor Age Categories**				
	< 10	**10 – 39**	**40 – 49**	**50 – 59**	**≥ 60**
CVA + HTN + Creat > 1.5				**X**	**X**
CVA + HTN				**X**	**X**
CVA + Creat > 1.5				**X**	**X**
HTN + Creat > 1.5				**X**	**X**
CVA					**X**
HTN					**X**
Creatinine > 1.5					**X**
None of the above					**X**

X=Expanded Criteria Donor
CVA=CVA was cause of death
HTN=history of hypertension at any time
Creat > 1.5 = creatinine > 1.5 mg/dl

3.5.2 ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients. Blood type O kidneys must be transplanted only into blood type O candidates except in the case of zero antigen mismatched candidates (as defined in Policy 3.5.3.1) who have a blood type other than O. Additionally, blood type B kidneys must be transplanted only into blood type B candidates except in the case of zero antigen mismatched candidates (as defined in Policy 3.5.3.1) who have a blood type other than B. Therefore, kidneys from a blood type O donor are to be allocated only to blood type O candidates and kidneys from a blood type B donor are to be allocated only to blood type B candidates, with the exception for zero antigen mismatched candidates noted above. This policy, however, does not nullify the physician's responsibility to use appropriate medical judgment in an extreme circumstance.

3.5.3 Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into UNet^{SM} prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.

3.5.3.3 Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1] if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1], if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after

Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

[1]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.3.3.1 First to identical blood type zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:

i local candidates; then to
ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii 80% or higher PRA candidates on the regional waiting list; then to
iv 80% or higher PRA candidates on the national waiting list; then to
v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
ix 21%-79% PRA candidates on the regional waiting list; then to
x 21%-79% PRA candidates on the national waiting list.

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched candidates, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and, then, to blood type A and AB zero antigen mismatched candidates, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all pediatric and sensitized adult candidates (CPRA > 20%) who are blood type compatible zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys,

as set forth in (i)-(xiv) below:

i local candidates; then to
ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii 80% or higher PRA candidates on the regional waiting list; then to
iv 80% or higher PRA candidates on the national waiting list; then to
v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
ix 21%-79% PRA candidates on the regional waiting list; then to
x 21%-79% PRA candidates on the national waiting list.

3.5.3.4 Kidney/Non-Renal Exception. When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. This exception does not apply to kidney-islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized candidates as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

3.5.3.5 Organ Offer Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNet℠ or through the Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). For standard criteria donor (SCD) kidneys, offers must be made for at least 10 zero antigen mismatched potential recipients.[1] If there are less than 10 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients. If there are less than 5 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

[1] For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. If the Host OPO chooses to share the zero antigen mismatch through UNet℠, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet℠. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.5.4 **Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates.** An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.

3.5.4.1 Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate Member for the candidate with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.

3.5.5 **Payback Requirements.** Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - Time Limit), 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor[1], six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[1]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than six.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated six or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than six.

3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.

3.5.6 Geographic Sequence of Deceased Kidney Allocation. In general, kidneys are to be allocated locally first, then regionally, and then nationally.

3.5.6.1 Local Allocation. With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to local candidates as defined in Policy 3.1.7 the locale where the kidneys are procured.

3.5.6.2 Regional Allocation. If a standard donor kidney is not accepted by any of the local transplant centers for local candidates, the kidney is to be allocated next via the regional list consisting of all candidates listed on the Waiting Lists of other Members within the same Region as the Member which procured the kidney. When a standard donor kidney is allocated regionally, it is to be offered

to Members for specific candidates in the region according to the point system described in Policy 3.5.11 in descending point order beginning with the candidate in the region who has been assigned the highest number of points. With all regionally-shared standard donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the candidate. Selection of alternate candidates must be according to the point system for standard kidney allocation. If a local potential recipient(s) who has agreed to receive expanded criteria donor kidneys is not identified (*i.e.*, a match run and process for notifying the appropriate transplant program(s) initiated) within six hours post cross clamping of the donor aorta, the kidney is to be allocated next via the regional list consisting of all candidates who have agreed to receive expanded criteria donor kidneys listed on the Waiting Lists of other Members within the same Region as the Member which procured the kidney. When an expanded criteria donor kidney is allocated regionally, it is to be offered to Members for specific candidates in the region according to the point system described in Policy 3.5.12 in descending point order beginning with the candidate who has agreed to receive expanded criteria donor kidneys in the region who has been assigned the highest number of points. With all regionally-shared expanded criteria donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the candidate. Selection of alternate candidates must be according to the point system for expanded criteria kidney allocation.

3.5.6.3 National Allocation. If a standard donor kidney is not accepted by any transplant center in the Region in which the Member which procured the kidney is located, the kidney is to be allocated to Members for specific candidates in the other Regions nationally according to the point system described in Policy 3.5.11 in descending point order beginning with the candidate who has the highest number of points. With all nationally shared standard donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that candidate. Selection of alternate candidates must be according to the point system for standard donor kidney allocation. If an expanded criteria donor kidney is not accepted by any transplant center in the Region in which the Member which procured the kidney is located, the kidney is to be allocated to Members for specific candidates who have agreed to receive expanded criteria donor kidneys in the other Regions nationally according to the point system described in Policy 3.5. 12 in descending point order beginning with the candidate who has the highest number of points. With all nationally shared expanded criteria donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that candidate. Selection of alternate candidates must be according to the point system for expanded criteria donor kidney allocation.

3.5.6.4 Regions. Members belong to the Region in which they are located. The Regions are as follows:

Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Region 2 - Delaware, District of Columbia, Maryland, New Jersey,

	Pennsylvania, Northern Virginia, West Virginia
Region 3 -	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 4 -	Oklahoma, Texas
Region 5 -	Arizona, California, Nevada, New Mexico, Utah
Region 6 -	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 7 -	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8 -	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 9 -	New York
Region 10 -	Indiana, Michigan, Ohio
Region 11 -	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

3.5.7 **Double Kidney Allocation.** Kidneys from adult donors must be offered singly unless the donor meets at least two of the following conditions and the OPO would not otherwise use the kidneys singly:

(i) Donor age greater than 60 years;
(ii) Estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission;
(iii) Rising serum creatinine (greater than 2.5 mg/dl) at time of retrieval;
(iv) History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus);
(v) Adverse donor kidney histology (defined as moderate to severe glomerulosclerosis (greater than 15% and less than 50%).

Kidneys offered for double kidney allocation will be allocated, first locally, then regionally, and then nationally, according to the sequence and point system described in Policies 3.5.6 and 3.5.11.

3.5.8 **Expanded Criteria Donor Kidney Allocation.** Kidneys from expanded criteria donors must be offered for candidates who have agreed to receive these organs in accordance with the geographic sequence of deceased kidney allocation set forth in Policy 3.5.6 and pursuant to the point system described in Policy 3.5.12.

3.5.9 **Minimum Information/Tissue for Kidney Offer.**

3.5.9.1 **Essential Information for Kidney Offers.** The Host OPO must provide the following information to the potential recipient center with each kidney offer:

(i) Donor name and Donor I.D. number, age, sex, and race;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(iv) Blood type;
(v) HLAA, B, Bw4, Bw6, and DR antigens;
(vi) Current history of abdominal injuries and operations;
(vii) Pertinent past medical or social history;
(viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
(ix) Final urinalysis;
(x) Final BUN and creatinine;
(xi) Indications of sepsis;
(xii) Assurance that final blood and urine cultures are pending;
(xiii) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
(xiv) Current medication and transfusion history;
(xv) Recovery blood pressure and urine output information;
(xvi) Recovery medications;
(xvii) Type of recovery procedure (e.g., en bloc); flush solution and method

(e.g., in situ); and flush storage solution;

(xviii) Description of typing material available, including, as a minimum for each kidney:
- One 7 to 10ml. clot (red topped) tube for ABO Verification, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm wedge of spleen in culture medium, if available

(xix) Warm ischemia time and organ flush characteristics; and

(xx) Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood

3.5.9.2 Desirable Information for Kidney Offers. With each kidney offer, the Host OPO or donor center is encouraged to provide the recipient center with the following biopsy information for all ECD kidneys and for all non-ECD kidneys at the request of the accepting surgeon. To ensure an optimal kidney biopsy, it is *recommended* that:

(i) the wedge technique be used;

(ii) the sample measures approximately 10mm (length) x 5mm (width) x 5mm (depth);

(iii) a minimum of 25 glomeruli are captured in the sample; and

(iv) a frozen section slide or the biopsy material accompanies the kidney for review.

3.5.10 [RESERVED]

3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the Match System, all candidates who have an ABO blood type that is compatible with that of the donor and who are listed as active on the Waiting List will be assigned points and priority as follows:

3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNet^{SM}; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNet^{SM} , including whether the candidate met the following criteria.

- measured (actual urinary collection) or calculated or creatine clearance or GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of chronic maintenance dialysis (defined as dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) candidate in a hospital based, independent (non-hospital based), or home setting).

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. While not required for purposes of initiating waiting time, programs shall report whether or not pediatric candidates are on dialysis, and if on dialysis, a dialysis start date. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

3.5.11.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local and regional lists.

3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a candidate based on the number of mismatches between the candidate's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:

- 2 points if there are no DR mismatches, as defined in the table below or;
- 1points if there is 1 DR mismatch as defined in the table below.

HLA Mismatch Definitions*

Mismatch Category	**# HLA Locus Mismatches**		
	A	**B**	**DR**
0 ABDR MM	0	0	0
0 DR MM	0	1	0
	0	2	0
	1	0	0
	1	1	0
	1	2	0
	2	0	0
	2	1	0
	2	2	0
1 DR MM	0	0	1
	0	1	1
	0	2	1
	1	0	1
	1	1	1
	1	2	1
	2	0	1
	2	1	1
	2	2	1

- Antigens that are considered to be equivalent for matching purposes are currently shown in ~~Appendix C of UNet℠ User's Manual.~~Appendix A to Policy 3.

NOTE: The amendments to Policy 3.5.11.2 (Quality of Antigen Mismatch) shall be effective following notice to the membership.

There is a pair of antigens at each HLA locus. Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus (i.e., When only one of the antigens in the pair at an HLA locus is identified, the other antigen is presumed to be identical). For example, a donor typed as A2, A-(blank) would be considered A2, A2. In the following example,

the recipient would receive 2 points for having a zero, DR mismatch (no mismatches at DR locus) because the recipient would not recognize any DR donor antigens as foreign.

Donor Phenotype	Recipient Phenotype
A23, A- (blank)	A1, A9
B7, B8	B7, B8
DR, DR4	DR1, DR4

3.5.11.3 Sensitized Wait List Candidates - Calculated PRA (CPRA). CPRA is the percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. Sensitized Waiting List candidates with defined unacceptable HLA antigens that yield a CPRA of 80% or greater will be assigned 4 points. Each transplant center may define the criteria for unacceptable antigens that are considered as contraindications for transplantation. Unacceptable antigens that are defined by laboratory detection of HLA specific antibodies must be determined using at least one solid phase immunoassay using purified HLA molecules. It is the prerogative of the transplant center to establish criteria for additional unacceptable antigens, such as repeat transplant mismatches. The CPRA will be calculated automatically when the unacceptable antigens are listed or updated on the Waiting List. The CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial/ethnic groups in proportion to their representation in the national deceased donor population.

3.5.11.4 Medical Urgency. No points will be assigned to candidates based upon medical urgency for regional or national allocation of kidneys. Locally, the candidate's physician has the authority to use medical judgment in assignment of medical urgency points if there is only one renal transplant center. When there is more than one local renal transplant center, a cooperative medical decision is required prior to assignment of medical urgency points.

3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. These points shall be assigned when the candidate is registered on the Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for

kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after Cardiac Death donor kidneys allocated regionally or nationally, four (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

3.5.11.6 Donation Status. A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting.

3.5.12 The Point System for Expanded Criteria Donor Kidney Allocation. When information about an expanded criteria donor is entered into the Match System, all candidates who have agreed to receive expanded criteria donor kidneys, have an ABO blood type that is compatible with that of the donor, and who are listed as active on the Waiting List will be assigned points and priority as follows:

3.5.12.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNet^{SM}; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNet^{SM}, including whether the candidate met the following criteria.

- measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of dialysis.

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

3.5.12.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local and regional lists.

3.5.13 **Choice of Right Versus Left Donor Kidney.** Except in the case of donor kidney(s) offered for zero antigen mismatched candidates under Policy 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) or for kidney and non-renal organ transplantation, the recipient center offered a kidney for a candidate based upon priority on the waiting list may select which of the two kidneys it will receive, if both kidneys from the donor are transplantable.

3.5.14 **Broad and Split Antigen Specificities.** HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in Appendix 3A. Appendix 3A will be updated annually by the Histocompatibility Committee. For matching purposes, split antigens not on this list will be indicated on the Waiting List as the parent antigens and will match only with the corresponding parent antigens. Laboratories are encouraged to assign all splits.

3.5.15 **Local Conflicts.** Regarding allocation of kidneys, 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 Kidney and Pancreas Transplantation Committee and Board of Directors.

3.5.16 **Allocation of Deceased Kidneys with Discrepant HLA Typings.** Allocation of deceased kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the donor, the kidney may be allocated in accordance with the original HLA typing, or the recipient center may reallocate the kidney locally, according to Policy 3.5.

3.5.17 **Prospective Crossmatching.** A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

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Editorial Comment

Eurotransplant kidney allocation system (ETKAS): rationale and implementation

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The Eurotransplant Kidney Allocation System (ETKAS)

Eurotransplant, founded by Jon J. van Rood in 1967, was initially only a registry of renal transplant candidates with the primary aim to optimize HLA matching. The organization has expanded continuously since then, and the current mission statement includes such goals as

- the achievement of an optimal use of available donor organs
- the guarantee of a transparent and objective recipient selection system based on medical criteria
- the assessment of the importance of factors, which have the greatest influence on transplant results
- the scientific research to improve the results of transplantation
- the support of donor procurement to increase organ supply
- the promotion, support and coordination of organ transplantation in the broadest sense of terms.

Nevertheless, one of the major tasks of Eurotransplant has remained the allocation of donor organs, probably the most sensitive and fragile issue in medicine – next to triage. Currently, more than 12 000 patients with end stage renal disease are registered for kidney transplantation and approximately 3300 transplantations are performed per year. The allocation rules used currently (Eurotransplant Kidney Allocation System or ETKAS) are based on a consensus among the participating countries Austria, Belgium, Germany, Luxemburg, the Netherlands and Slovenia, representing a population close to 118 million. ETKAS was implemented in 1996 and has been refined continuously since then in order to shorten the average and maximum waiting times, adjust for rare HLA phenotypes and homozygosity, achieve a reasonable balanced kidney exchange rate among countries and guarantee an acceptable HLA match distribution and optimal overall transplant success rate.

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Organ allocation in ETKAS

All kidneys (including organs from non-heart-beating donors in all countries with the exception of Germany) procured in the Eurotransplant region are allocated using the algorithms delineated below. However, combined transplantations of a kidney and a non-renal organ have priority over all categories of kidney only transplantations.

Urgency codes and special programmes

Transplant candidates can be classified on the waiting list using urgency codes. These codes combine aspects of transplantatibility, (yes or no, i.e. not transplantable or NT), medical urgency, (high urgency or HU) and the most recent level of allosensitization (<6% of panel reactive allo-antibodies, transplantable or T, ≥6 but <85%, immunized or I, and >85%, highly immunized or HI). In order for a patient to be accepted by Eurotransplant as a candidate for HU, specific inclusion criteria have to be met (such as lack of access to either haemodialysis or peritoneal dialysis, severe neuropathy etc.).

Furthermore, candidates can be registered within special subprogrammes. The Acceptable Mismatch (AM) programme, which is run for every deceased kidney donor, includes patients with a history of a percentage of panel reactive antibodies ≥85% in two consecutive 3 monthly screenings. The patients do not necessarily need to be highly immunized at the time of organ matching. The programme identifies HLA-A, -B and -DR mismatches not resulting in a positive cross

match by identifying the HLA-A, -B and -DR antigens against which the recipient has not yet reacted with allo-antibodies. Further minimum requirements for organ allocation are sharing of one HLA-B and -DR antigen, no unacceptable donor antigens and repeated mismatches and a negative cross match result in currently sensitized AM patients.

The Eurotransplant Senior programme (ESP) allocates kidneys from ≥65-year-old deceased donors to ≥65-year-old recipients. In order to keep the cold ischaemia time as short as possible, no HLA typing is performed, and the organs are transplanted on a local (Austria, Belgium/Luxemburg, Slovenia), regional (Germany) or national (Netherlands) level. Kidneys are reported to ETKAS after HLA typing only if they cannot be allocated within ESP.

Blood group rules

AB0 incompatible kidney transplants are not allowed. Within the AM programme AB0 compatibility is mandatory (i.e. A to A and AB, B to B and AB, AB to AB and 0 to A, B and AB). Blood group 0 000 HLA mismatch grafts and organs within the ESP programme can be allocated to B and 0 recipients. For patients with ≥1 HLA mismatch blood group 0 kidneys are matched to blood group 0 recipients only.

ETKAS point score system

For kidneys that are not allocated via ESP, potential recipients are searched first within the AM programme. If no suitable candidate can be identified, the search continues by looking for patients with a complete HLA match. If several of these are available, they are ranked with the help of a point score system as are all others in case no 000 HLA match can be obtained. The patient with the highest point score is ranked on top and receives the first offer. If this offer is rejected all following offers are made in descending order. The number of points awarded is based on several variables, which include the urgency status, HLA match grade, mismatch probability, waiting time, a distance factor and the national balance. Transplant candidates with the urgency code HU receive a bonus of 500 points. Paediatric patients (<16 years old at the time of registration) receive a bonus according to their age at the time of registration (<6 years 100 points, ≥6–11 years 33.3 points and ≥11 and <16 years 66.6 points). Additionally, the points for HLA antigen matching are doubled for children. In general, each HLA-A, -B and -DR antigen shared is rewarded 66.67 points. The mismatch probability is a calculation of the probability of receiving a kidney offer with 0 and 1 broad HLA-A, -B or -DR mismatch based on 1000 kidneys offered taking into account the AB0 blood group rules and the PRA screening using data from the Collaborative Transplant Study database for a Caucasian donor population. Upon registration, the patients date of the first dialysis or date of re-institution of dialysis after a previous kidney transplantation is counted as the first day for the calculation of the waiting time. A patient, who is registered with the immediate previous kidney transplantation having failed within 3 months after transplantation is eligible for the return of waiting time. Per year waiting time in all countries, except Germany, 33.3 points can be acquired. The points for Germany are different (50) to compensate for the difference in points acquired for the regional bonus (see below). Pre-emptive transplant candidates can be registered, but receive no points for waiting time as they have not yet started dialysis. Local recipients (i.e. candidates from the center where the donor is from) receive a bonus of 100 points in Belgium/Luxemburg and Slovenia and 200 points in Austria. In Belgium/Luxemburg and Slovenia, a regional bonus (one or more transplant centers in the same region of the donor center) of 100 and in Germany of 200 points is appointed. Patients in Austria, Belgium/Luxemburg and Slovenia additionally receive 100 national points. All Dutch patients receive 300 national points. Thus all patients, except from Germany, receive a total of 300 points for local, regional and national points. The German patients (200 points) are therefore compensated via the waiting time with 50 points per year. Once every working day for the period of the immediately preceding 365 days, the difference between the number of kidneys procured and exchanged for transplantation in and between each country is calculated. A negative balance for a country is defined as more kidneys being procured than transplanted, a positive balance is the other way around. The national balance points are then calculated as the highest import balance minus the recipient country balance times 10.

Consequences of the Implementation of ETKAS

Before ETKAS was implemented in 1996, several goals were defined. The new system should shorten the average and especially maximum waiting time. Indeed, since then about 36% of the kidneys were transplanted into recipients with a waiting time of more than 5 years, a number twice as high as before 1996. Furthermore, a reasonably balanced kidney exchange rate among participating countries is maintained. Prior to the initiation of ETKAS in March 1996, Austria had a negative balance of 25 kidneys, Belgium and Luxemburg of 57 and the Netherlands of 42. Germany on the contrary had a positive balance of 136. On 11 March 2005, the corresponding numbers were only +6, −2, +4, and +11, respectively. Despite this, the HLA match distribution has remained stable (e.g., 22% 000 HLA mismatched patients) and the 1 and 3 year kidney graft survival is good. Finally, it turned out to be very successful for children.

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Transplanting the highly sensitized patient: The emory algorithm.

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Abstract

Renal transplant patients sensitized to HLA antigens comprise nearly one-third of the UNOS wait-list and receive 14% of deceased donor (DD) transplants, a rate half that of unsensitized patients. Between 1999 and 2003, we performed 492 adult renal transplants from DD; 120 patients (approximately 25%) had a panel reactive antibody (PRA) of >30%, with nearly half (n = 58) having a PRA of >80%. Our approach is based upon high-resolution solid-phase HLA antibody analysis to identify class I/II antibodies and a 'virtual crossmatch' to predict compatible donor/recipient combinations. Recipients are excluded from the United Network for Organ Sharing match run if donors possess unacceptable antigens. Thus, when sensitized patients appear on the match run, they have a high probability of a negative final crossmatch. Here, we describe our 5-year experience with this approach. Five-year graft survival ranged from 66% to 70% among unsensitized (n = 272), moderately sensitized (PRA < 30%, n = 100) and highly sensitized (>30% PRA; n = 120) patients, equal to the average national graft survival (65.7%). The application of this approach (the Emory Algorithm) provides a logical and systematic approach to improve the access of sensitized patients to DD organs and promote more equitable allocation to a highly disadvantaged group of patients awaiting renal transplantation.

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Review of the Uruguayan Kidney Allocation System: the solution to a complex problem, preliminary data.

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Abstract

The National Kidney Transplant Program with cadaveric donors is based on centralized and unique waitlist, serum bank, and allocation criteria, approved by Instituto Nacional de Donación y Trasplante (INDT) in agreement with clinical teams. The median donor rates over last 3 years is 20 per million population and the median number of waitlist candidates is 450. The increased number of waiting list patients and the rapid aging of our populations demanded strategies for donor acceptance, candidate assignment, and analysis of more efficient and equitable allocation models. The objectives of the new national allocation system were to improve posttransplant patient and graft survivals, allow equal access to transplantation, and reduce waitlist times. The objective of this study was to analyze variables in our current allocation system and to create a mathematical/simulation model to evaluate a new allocation system. We compared candidates and transplanted patients for gender, age, ABO blood group, human leukocyte agents (HLA), percentage of reactive antibodies (PRA), and waiting list and dialysis times. Only 2 factors showed differences: highly sensitized and patients >65 years old (Bernoulli test). An agreement between INDT and Engineering Faculty yielded a major field of study. During 2008 the data analysis and model building began. The waiting list data of the last decade of donors and transplants were processed to develop a virtual model. We used inputs of candidates and donors, with outputs and structure of the simulation system to evaluate the proposed changes. Currently, the INDT and the Mathematics and Statistics Institute are working to develop a simulation model, that is able to analyze our new national allocation system.

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Renal transplantation of highly sensitised patients via prioritised renal allocation programs. Shorter waiting time and above-average graft survival.

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Abstract

BACKGROUND: Highly sensitised renal transplant candidates (HSP) have a reduced chance of receiving a transplant. In Eurotransplant (ET), two special allocation programs have been made available for such patients: the Highly Immunised Tray (HIT) program and the Acceptable Mismatch program (AM), albeit with different inclusion and exclusion criteria (HIT, current PRA% >or=85%; AM, current and/or historical PRA% >or=85%). When a suitable kidney is available for a patient, included in these special programs, the kidney is mandatory offered. In contrast, in the point score system of the standard ET kidney allocation procedure (ETKAS), HSP (PRA >or=85%) only get a marginal bonus according to their current sensitisation. It was tested whether the allocation priority of the two special allocation programs is justified from the perspective of transplant outcome.

METHODS: The post- transplant outcomes of recent consecutive cohorts of AM, HIT and HSP-ETKAS transplants were compared. The end points were initial graft function, rejection episodes during the first three months post-transplant, and 1-year kidney graft outcome.

RESULTS: Between January 1, 1997 and June 30, 1998, 101 HSP received a kidney-only transplant: 29 via AM, 39 via HIT and 33 via ETKAS. HLA-A,B,DR matching was more favourable in the AM and HIT allocation groups and their waiting times till transplantation were much shorter than those of the HSP-ETKAS allocation group. The incidence of initial graft non-function was similar among the three HSP allocation groups, averaging 50%. Recovery of the initial non-function was more likely for AM and HIT transplants. No difference was present with regard to the percentage of patients who experienced at least one rejection episode during the first three months post-transplant, averaging 43%. However, the AM group had less severe and/or less recurrent rejection episodes. The 1-year kidney graft survival, censored for death with functional graft, was 96% for AM, 82% for HIT and 75% for HSP-ETKAS transplants ($p = 0.04$).

CONCLUSIONS: The two special allocation programs for HSP do yield adequate results and offer a shorter waiting time, compared to the standard kidney allocation procedure. The AM approach might be preferred because of the smoother post-transplant management and the better graft survival, keeping the HIT approach as a back up. Since the allocation priority is justified in view of efficiency, the renal transplant community should support the incorporation of a special allocation program for HSP in their respective organ exchange program.

Transplantation. 1997 Sep 27;64(6):860-4.

The high grade match kidney sharing algorithm of the South-Eastern Organ Procurement Foundation (SEOPF): altering recipient demographics through improved matching.

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Abstract

BACKGROUND: Studies of kidneys shared through the South-Eastern Organ Procurement Foundation (SEOPF) have shown that regional organ procurement (ROP) trays can predict negative crossmatch in highly sensitized patients when the HLA match is of a high grade. In an attempt to offer more well-matched kidneys to highly sensitized patients, SEOPF organized the High Grade Match (HGM) Program.

METHODS: This United Network for Organ Sharing (UNOS)-approved allocation variance requires mandatory sharing of all kidneys by participating centers after UNOS mandatory sharing requirements have been met. The HGM levels of sharing are: (1) 0 A,B mismatch (MM); panel-reactive antibody (PRA) > or = 40%; negative ROP crossmatch; (2) 0 B,DR MM with > or = 40% PRA; negative ROP crossmatch; (3) 0 B,DR MM with PRA < 40%. Non-HGM cadaveric transplants at the same participating centers--locally or distally procured--serve as the control group.

RESULTS: During the first 18 months of this program, the 23 participating centers shared 124 kidneys of the 1592 that were available. Well-matched kidneys (two mismatches or less) accounted for 91.1% in the HGM group, but only 19% of the controls (P<0.0001). Highly sensitized patients (PRA > or = 40%) represented 13.8% of the HGM group, but only 3.3% of the non-HGM group (P<.0001). With HGM kidneys, there was a shift in recipient demographics. Patients with blood group O, female patients, older patients, and retransplanted patients all accounted for significantly larger percentages of the HGM group compared with the non-HGM control group. The racial composition of the recipients of high-grade matches was, however, no different than that of the control recipients at the same centers.

CONCLUSION: The HGM Program resulted in longer ischemia times, but graft survival was not affected. The 1-year actuarial graft survival rate (Kaplan-Meier) for HGM kidneys was not different from the control cadaveric graft survival rate. By sharing kidneys based on improved HLA matches with consideration for high PRA, the HGM Program offered more transplant opportunities to women, blood group O recipients, retransplants, and older patients.