

Expanded Criteria Donors for Kidney Transplantation

The following text and data is an abbreviated version from University Renal Research and Education Association; United Network for Organ Sharing. 2002 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1992-2001 [Internet]. Rockville (MD): Department of Health and Human Services, Health Resources and Services Administration, Office of Special Programs, Division of Transplantation; 2003 [modified 2003 Feb 18; cited YYYY MMM D]. Available from: <http://www.optn.org/data/annualReport.asp>.

Overview

ドナー数の減少により生じている腎移植待機患者数と腎移植数との格差の増大により、これまでのクライテリアにおいて、比較的移植に不向きとされていた提供腎にも適応を増加させることが検討された。これらの拡大ドナー基準（ECD : expanded criteria donor）による移植腎が待機患者の余命と比較した際に、移植患者の余命が延長される事が明らかにされている。しかしながら、多くの場合、これらの基準に適合するレシピエントを選択することは困難であり、これらの腎の多くは移植医からの拒絶や冷阻血時間の延長等の理由により廃棄されている。新たに制定された画一的 ECD の定義では、マージナルドナーの腎臓の移植数が増加することが期待され、幹旋システムが効果的に機能すると思われる。

Characteristics of expanded and standard donors, and differences between them

The ideal deceased organ donor is a younger person who dies from traumatic head injury that is isolated to the brain and leaves the thoracic and abdominal organ function intact. These deceased donors provide excellent transplantable organs with an opportunity to achieve immediate allograft function and long-term patient survival. As the size of the recipient waiting list and the number of waiting list deaths increase, older donors and donors with characteristics once thought to preclude organ donation are being used more and more frequently (1).

Kidneys transplanted from older donors are considered to be from the expanded pool because these allografts have a higher rate of delayed graft function, more acute rejection episodes, and decreased long-term graft function. Several factors, including prolonged cold ischemia time (CIT), increased immunogenicity, impaired ability to repair tissue, and impaired function with decreased nephron mass may contribute to this (4). But recently, Ojo et al. have demonstrated that the recipients of expanded kidneys receive the benefit of extra life-years when compared to wait-listed dialysis patients (5). Still, placement of these organs is often difficult and delayed, and some centers continue to prefer not to utilize them (6).

The Kidney Work Group (7) noted that in recent years the discard rate of kidneys from deceased donors has increased substantially and approaches 50% for kidneys recovered from donors over age 60. They estimated a potential increase of 38% in the rate of donors per million population if the United States could match Spain's rate of recovery of kidneys from donors over age 45. The work group recommended, and the conference participants endorsed, expedited placement of kidneys from all donors over age 60, based upon waiting time only, to a list of pre-selected and pre-informed recipients who would accept these kidneys.

Findings to determine the utility of either or both in predicting immediate and long-term function of the older donor's kidney.

The result of their interaction with the Crystal City Kidney Group was to define the ECD based upon not only age but also using other statistically significant risk factors determined by the SRTR analyses. Three additional significant donor medical risk factors were identified: history of hypertension, cerebrovascular accident as a cause of death, and final pre-procurement creatinine > 1.5 mg/dl. Donor kidneys were characterized according to combinations of these four parameters, and a relative risk of graft loss was determined for each donor profile. The ECD kidney was then precisely defined as any kidney whose relative risk of graft failure exceeded 1.7 when compared to a reference group of ideal donor kidneys: those from donors of age 10-39 years, who were without hypertension, who did not die of a cerebrovascular accident, and whose terminal predonation creatinine level was <1.5 mg/dl (Table X-1). Using this definition based on the relative risk of graft loss, all donors over age 60 and donors aged 50-59 with at least two of the three medical criteria are identified as ECDs (Table X-2) (8).

The policy states, "Kidneys procured from the ECD will be allocated to patients determined to be suitable

candidates: first, for zero antigen mismatched patients among this group of patients with time limitations; and next, for all other eligible patients locally, regionally, and nationally, based upon time waiting and not HLA matching.

C. Comparison of the reasons for discard of expanded versus standard donor kidneys

During the past five years, the discard rate has increased from 12% to 15% — mostly because of the increase in the number of donors older than 50, who now represent over 30% of the national donor population.

D. Should biopsies play such an important role?

The correlation of kidney biopsy findings with immediate and long-term function remains both controversial and influential.

E. Who has received expanded criteria kidneys?

Recipients over the age of 50 (18%) were more likely to receive an ECD kidney than patients under the age of 50 (7%), while recipients who had had a prior kidney or kidney-pancreas transplant were less likely to receive an ECD kidney (8% and 13%, respectively). ECD transplants were less likely to have a 0 HLA mismatch than non-ECD transplants (8% and 13%). Recipients with ESRD due to diabetes or hypertension were more likely to receive an ECD kidney compared to those whose ESRD was caused by glomerulonephritis (14%, 14%, and 10%, respectively). Gender, race, blood type, and PRA at transplant were not associated with significant differences in the use of ECD kidneys.

F. How well have the ECD kidneys worked?

Graft survival of ECD kidney transplants is by definition inferior to that of standard kidney transplants. Unadjusted (Kaplan-Meier) graft survival estimates at three months and one year for 1,958 ECD kidney transplants performed in 1999 and 2000 are 90% and 82%, respectively (Table X-7).

Table X-7.

Graft Survival for Expanded Criteria Donor Kidney Transplants at 3 Months, 1 Year, 3 Years, and 5 Years

Categories		3 Months		1 Year		3 Years		5 Years	
		N	%	N	%	N	%	N	%
Total	All	1,958	90.4%	1,958	81.7%	1,909	85.1%	1,698	48.6%
Age (Years) at Tx	<1 Year	0	-	0	-	0	-	0	-
	1-5 Years	1	*	1	*	1	*	2	*
	6-10 Years	2	*	2	*	2	*	4	*
	11-17 Years	7	*	7	*	11	80.8%	9	*
	18-34 Years	177	88.0%	177	79.9%	186	68.2%	219	44.7%
	35-49 Years	464	92.7%	464	84.3%	519	70.7%	564	52.4%
	50-64 Years	927	91.2%	927	82.6%	891	64.8%	678	47.8%
Recipient Race	65+ Years	380	87.4%	380	77.5%	299	53.9%	222	45.2%
	White	1,232	90.5%	1,232	82.4%	1,246	67.2%	1,139	50.5%
Recipient Ethnicity	Asian	110	94.4%	110	88.6%	95	72.8%	70	63.7%
	African American	576	89.8%	576	79.5%	541	59.4%	465	42.0%
	Other/Multi-race	40	82.1%	40	71.0%	27	58.2%	24	38.4%
Recipient Gender	Hispanic/Latino	217	94.9%	217	89.5%	212	75.3%	157	51.2%
	Non-Hispanic/Non-Latino	1,705	90.1%	1,705	81.0%	1,610	63.6%	1,432	48.4%
Previous Kidney Tx	Unknown	36	76.8%	36	64.5%	87	69.0%	109	47.5%
	Female	786	91.3%	786	83.7%	755	66.4%	651	49.8%
PRA at Transplant	Male	1,172	89.7%	1,172	80.3%	1,154	64.3%	1,047	47.9%
	No	1,772	90.6%	1,772	82.1%	1,719	65.6%	1,523	49.1%
Dialysis Needed Within First Week After Tx	Yes	186	87.8%	186	77.9%	180	60.0%	175	44.4%
	0-19%	1,594	90.6%	1,594	82.2%	1,587	66.4%	1,454	49.5%
	20-79%	138	89.6%	138	77.2%	129	53.2%	108	48.4%
	80%+	58	84.5%	58	69.9%	51	59.5%	42	23.1%
Level of HLA Mismatch	Unknown	168	90.4%	168	84.1%	142	63.0%	94	47.5%
	No	1,276	95.5%	1,276	88.4%	1,183	71.8%	1,002	57.7%
	Yes	557	88.8%	557	76.0%	621	60.3%	609	39.2%
Level of HLA Mismatch	Unknown	39	92.2%	39	71.5%	23	58.7%	15	40.7%
	0	240	89.9%	240	83.4%	231	70.3%	218	57.0%
	1	71	92.8%	71	83.5%	76	67.5%	659	42.4%
	2	219	92.9%	219	83.9%	237	64.6%	242	44.2%
	3	396	92.9%	396	85.3%	432	67.6%	381	49.2%
	4	487	89.0%	487	78.1%	468	63.6%	419	44.7%
	5	366	90.0%	366	81.5%	306	60.1%	263	52.0%
	6	171	85.0%	171	77.5%	155	64.1%	120	47.0%
Unknown	8	*	7	*	4	*	6	*	

Source: OPTN/SRTR data as of August 1, 2002.

Notes:

(*) = Values suppressed due to small N (0 to 9).

Cohorts are transplants performed during 1999-2000 for 3 month and 1 year; 1997-1998 for 3 year; and 1995-1996 for 5-year survival. Graft survival follows individual transplants until graft failure. Counts for patient and graft survival are different because a patient may have more than one transplant for a type of organ. Multi-organ transplants are excluded.

Although both donor age and prolonged cold ischemia time have been associated with increased risk of delayed graft function, cold ischemia time appears to have little additive effect on one- and three-year graft function and survival (16). Most authors suggest that ECD kidneys should be used locally, to minimize any detrimental effect of cold ischemia time on graft function and survival. The new OPTN/UNOS algorithm for allocation of ECD kidneys favors reducing cold

ischemia time over HLA matching. In an analysis of donor characteristics used in formulating the new ECD definition, Port et al. have shown that the benefits of a shorter cold ischemia time slightly outweigh the benefits of HLA matching (8) (Table X-9).

G. Who Should Be Offered the ECD KIDNEYS?

The group suggested that ECD kidneys should be preferentially directed toward candidates older than 60, diabetic candidates older than 40, candidates with failing vascular access, and candidates whose expected waiting time exceeds their life expectancy on the waiting list without a transplant.

Table X-10.
Patient Survival for Expanded Criteria Donor Kidney Transplants at 3 Months, 1 Year, 3 Years, and 5 Years

Categories		3 Months		1 Year		3 Years		5 Years	
		N	%	N	%	N	%	N	%
Total	All	1,772	96.0%	1,772	90.6%	1,729	78.5%	1,523	69.9%
Age (Years) at Tx	<1 Years	0	-	0	-	0	-	0	-
	1-5 Years	1	*	1	*	0	-	2	*
	6-10 Years	1	*	1	*	2	*	2	*
	11-17 Years	4	*	4	*	11	100.0%	9	*
	18-34 Years	129	98.4%	129	96.9%	144	93.1%	172	87.6%
	35-49 Years	391	98.5%	391	95.4%	446	86.3%	482	77.8%
	50-64 Years	874	95.4%	874	89.5%	836	76.7%	639	63.5%
	65+ Years	372	93.8%	372	85.8%	290	63.8%	217	55.5%
Recipient Race	White	1,103	95.9%	1,103	90.1%	1,110	77.6%	1,002	69.0%
	Asian	99	98.0%	99	92.9%	92	85.9%	66	80.3%
	African American	531	96.0%	531	91.7%	502	79.3%	431	71.7%
	Other/Multi-race	39	92.3%	39	82.1%	25	80.0%	24	46.7%
Recipient Ethnicity	Hispanic/Latino	204	97.5%	204	95.1%	195	82.1%	146	70.2%
	Non-Hispanic/Non-Latino	1,538	96.0%	1,538	90.2%	1,456	78.1%	1,281	70.6%
	Unknown	30	83.3%	30	80.0%	78	78.2%	96	60.0%
Recipient Gender	Female	708	96.3%	708	91.8%	677	79.3%	586	71.8%
	Male	1,064	95.8%	1,064	89.8%	1,052	78.0%	937	68.7%

Source: OPTN/SRTR Data as of August 1, 2002.

Notes:

(*) = Values suppressed due to small N (0 to 9).

Cohorts are transplants performed during 1999-2000 for 3 month and 1 year; 1997-1998 for 3 year; and 1995-1996 for 5-year survival. Patient survival follows patients from first transplant of this type until death. Counts for patient and graft survival are different because a patient may have more than one transplant for a type of organ. Multi-organ transplants are excluded.

Table X-11.

Patient Survival for Non-Expanded Criteria Donor Kidney Transplants at 3 Months, 1 Year, 3 Years, and 5 Years

Categories		3 Months		1 Year		3 Years		5 Years	
		N	%	N	%	N	%	N	%
Total	All	11,899	97.5%	11,899	94.5%	11,671	89.9%	11,592	81.2%
Age (Years) at Tx	<1 Year	1	*	1	*	0	-	0	-
	1-5 Years	78	98.7%	78	97.4%	74	93.2%	81	92.6%
	6-10 Years	86	96.5%	86	96.5%	116	98.3%	98	93.3%
	11-17 Years	329	99.7%	329	99.4%	267	97.8%	321	95.0%
	18-34 Years	1,928	99.2%	1,928	97.9%	1,943	96.3%	2,202	90.4%
	35-49 Years	3,932	98.5%	3,932	96.6%	4,219	92.5%	4,308	84.8%
	50-64 Years	4,410	96.4%	4,410	92.3%	4,113	86.2%	3,794	74.7%
	65+ Years	1,135	94.6%	1,135	88.7%	939	77.6%	788	59.0%
Recipient Race	White	7,599	97.5%	7,599	94.6%	7,538	90.0%	7,618	81.1%
	Asian	581	97.6%	581	95.4%	579	92.6%	495	88.0%
	African American	3,489	97.5%	3,489	94.3%	3,342	89.2%	3,248	80.4%
	Other/Multi-race	230	98.3%	230	95.2%	210	90.0%	231	81.3%
	Unknown	0	-	0	-	2	*	0	-
Recipient Ethnicity	Hispanic/Latino	1,469	97.3%	1,469	95.0%	1,351	93.6%	1,340	85.1%
	Non-Hispanic/Non-Latino	10,250	97.5%	10,250	94.5%	9,887	89.5%	9,572	80.8%
	Unknown	180	96.1%	180	93.9%	433	86.8%	680	78.8%
Recipient Gender	Female	4,722	97.5%	4,722	94.8%	4,632	90.6%	4,433	82.0%
	Male	7,177	97.5%	7,177	94.4%	7,039	89.4%	7,159	80.7%

Source: OPTN/SRTR Data as of August 1, 2002.

Notes:

(*) = Values suppressed due to small N (0 to 9).

Cohorts are transplants performed during 1999-2000 for 3 month and 1 year; 1997-1998 for 3 year; and 1995-1996 for 5-year survival. Patient survival follows patients from first transplant of this type until death. Counts for patient and graft survival are different because a patient may have more than one transplant for a type of organ. Multi-organ transplants are excluded.

H. How should we evaluate the effectiveness of the new allocation process for ECD kidneys?

Data regarding graft function and patient and graft survival should be readily reported and available so that the OPTN and SRTR can easily monitor the effects of this allocation policy. Such a system could examine the policy's impact on reducing the CIT of ECD kidneys and whether the duration of CIT influences the rate of immediate function of ECD kidneys following transplantation (when compared to standard donor kidneys transplanted within the same OPO). Resolving the question on the importance of organ morphology will be more difficult and will require the design of single-center, multi-center, and/or OPO wide studies to address this issue.

It is likely that additional donor categories will be added to the definition of the ECD. At the time of the initial analysis for 1995-2000, the number of nonheartbeating donors (donors after cardiac death) in the database accounted for only 1.5% of kidney transplants. For this selected group, the relative risk of graft failure was significantly elevated but

appeared to be less than 1.7. By contrast, the odds of delayed graft function exceeded 2.0 for kidneys from nonheartbeating donors (F. Port, personal communication). As the use of nonheartbeating donors increases over time, these analyses will need to be repeated.

I. Conclusion

The expedited allocation of ECD kidneys depends strongly upon two elements of the new policy. First, the substantial de-emphasis of immunologic matching concomitant with the primacy of waiting time results in a more predictable lineup of potential recipients. Transplant centers can then ensure that candidates listed for ECD kidneys with the longest waiting time for each blood group are fully evaluated and thereby ready to proceed with transplantation. Second, and perhaps more controversial, is the requested assurance of prior informed consent for every candidate listed for an ECD kidney. Specific informed consent appears wise since the transplantation of an ECD kidney implies additional graft failure risk, which exceeds standard expectations.

Currently, ECD kidneys are often refused for transplantation; refusals prolong cold ischemia and often result in organ discard. It is presumed that a common reason for refusal of an ECD kidney is that the transplant physician does not consider it appropriate for the particular candidate to which it has been offered. It is also possible that the candidate, after discussion with his or her transplant physician, has refused the kidney, choosing to wait for a better organ. Prior informed consent aims to substantially reduce the occurrence of the above scenarios and thereby expedite organ placement. Thoughtful consideration and discussion for both the transplant program and the candidate can occur "in the light of day" and over time, outside of the pressured time frame of a specific organ offer. Therefore, listing of a particular candidate for an ECD kidney would indicate that the transplant center considers that individual appropriate for transplantation with an ECD kidney and that the candidate will accept transplantation with an ECD kidney.

添付資料— 3

Guidance on the Microbiological Safety of Human Organs, Tissues and cells used in Transplantation. Advisory Committee on the Microbiological safety of Blood and Tissues for Transplantation MSBT, Department of Health, 2000 (UK)

Preface より

This guidance updates and replaces the 'Guidance on the Microbiological Safety of Human Tissues and Organs used in Transplantation' issued in 1996 by the Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT). The role of MSBT is to reduce to a minimum the risk of transmission of infection through transplantation.

The guidance has been written by a working group (members of which are listed in annex 6) after extensive consultation.

The underlying principle running through the guidance is that the risk of infection being passed on through transplanted organs, tissues and cells should be kept to a minimum, taking account of the balance of risk and benefit for the person receiving the transplant. In urgent life-saving situations a higher risk of infection may be acceptable; stricter controls are needed in non-urgent situations and for transplants aimed at improving a patient's quality of life rather than saving it.

The main recommendations covering organs, tissues and cells from an infected (or potentially infected) donor are contained in tables 3, 4 and 5.

The information requirements for assessing a donor's risk of infection are set out in annex 2. Where appropriate, this guidance follows the recommendations for testing blood donors. However, there are some situations (particularly in urgent organ donation), where the testing of potential donors will be different. These situations, and the testing that will need to be carried out, are set out in this guidance.

This is a developing area and the guidance reflects best practice in accordance with available evidence, supplemented by expert opinion where published evidence is lacking. This guidance acknowledges those areas that are contentious and recognises that further work and debate are needed. The recommendations in this guidance need to be regularly reviewed, for example around the introduction of nucleic acid testing and the present uncertainties about the transmissible spongiform encephalopathies.

This guidance challenges those involved in transplantation to turn the recommendations into working clinical tools.

表1 MSBTでのヒト伝達性海綿状脳症の取り扱い(上記より抜粋)

感染症	臨床状況	臓器	組織	細胞
ヒト伝達性海綿状脳症 (Transmissible spongiform encephalopathies: TSE)	すべてのタイプのTSEについての確定診断、または強い疑い	提供禁忌	提供禁忌	提供禁忌
	Classic CJD のリスクファクター	原則的には提供は禁忌であるが、レシピエントが生命の危険に晒されている場合には、レシピエント及び近親者と十分な説明をした上で可能。	提供禁忌	原則的には提供は禁忌であるが、骨髄移植レシピエントが生命の危険に晒されている場合には、レシピエント及び近親者と十分な説明をした上で可能。

表2 MSTBで定めるヒト伝達性海綿状脳症のリスクファクター(上記より抜粋)

リスクファクター	内容・解説
CJD/vCJD、Gerstmann-Straussler-Schienker 病の家族歴	Classic CJD の 15%は家族歴陽性である。家族歴陽性の場合には提供禁忌。
1989 年以前にヒト由来の脳下垂体成長ホルモン及びゴナドトロピンの投与歴がある場合	Classic CJD の患者の脳が混入した可能性があるため。
過去に眼球組織の移植(角膜、胸膜、眼球幹細胞)を受けた場合	Classic CJD は角膜移植による感染例がある。過去に眼球組織の移植を受けた場合には眼球組織の提供はできない。
1992 年以前に、脳神経外科手術、脊髄腫瘍・のう胞の手術、硬膜移植術を受けた場合	脳神経外科手術ではしばしば硬膜を用いる。1992 年 8 月以前の硬膜では死体由来のものが使用され、これは classic CJD を感染させることが知られている。1992 年 8 月以降は使用されていない。二分脊髄、脊椎症の手術には通常硬膜は使用しない。
原因不明の神経変性疾患の罹患	提供は禁忌。
多発性硬化症、パーキンソン病、サルコイドーシス、クローン病などの原因不明の疾患の	未知の感染源がこれらの疾患の原因である可能性があるため。

罹患	
全身性疾患に伴う脳炎の既往を有し、かつ過去 6-12 カ月の間に海外渡航歴または海外での動物咬傷を有する	<ul style="list-style-type: none"> ・ 狂犬病：痙攣を伴わないもの(aphathetic)はしばしば見逃される。 ・ 単純ヘルペス：子供以外では全身性感染を生じることは稀 ・ 未知のウイルス：更に検索が必要

Recently Identified blood Borne Viruses

MSBT considered a paper summarising recently identified blood borne viruses. This noted that there is no country in the world testing for these viruses and that more research is underway to understand the possible impact of these agents and how they might be carried out if appropriate.

MSBT advised that the position should be kept under review and that a further formal paper be considered again next year

Revised Blood Safety Leaflet

MSBT considered a revised draft version of the UK Blood Service Blood Safety Leaflet. The leaflet had been revised to make it more explicit to risk behaviours rather than risk groups. MSBT raised concerns about wording of the revision and recommended that the Expert Advisory Group on AIDS (EAGA) should endorse the leaflet before MSBT signed off.

MSBT agreed to review the leaflet following EAGA's consideration.

High Court Judgement on hepatitis C

The High Court Judgement made on 26 March 2001 awarded damages to 114 people infected with hepatitis C through blood transfusion before the introduction of universal screening for the virus in 1991. The case was brought under the Consumer Protection Act 1987.

MSBT noted that the Department of Health were looking at the wider implications of the Judgement on the NHS.

Draft Blood Directive

MSBT was updated on the progress of the EC Draft Blood Directive. A number of reservations about the Draft Directive remained and consultation on further drafts would continue.

Better Blood Transfusion

MSBT noted that a second CMOs "Better Blood Transfusion" conference would take place later in the year. The conference is to be a collaboration UK wide involving the UK Departments of Health, the UK Blood Services and the National Audit Office.

MSBT noted the arrangements and asked to be kept informed of progress.

Notes to Editors

1. The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) was set up in 1993. Its terms of reference are "To advise the Health Departments of the UK on measures to ensure the microbiological safety of blood and tissues for transplantation. In making recommendations in relation to blood, the Committee will bear in mind the need for maintaining an adequate supply of blood of appropriate quality for both immediate use and for plasma processing."

2. In July 1998 the Government instructed the UK blood services to implement a programme of removing the white cells from donated blood (leucodepletion), as a practical precautionary measure to reduce the theoretical risk to the blood supply of the transmission of variant CJD following advice from the Spongiform Encephalopathy Advisory Committee (SEAC).

3. The use of non UK- sourced plasma followed the confirmation from the Committee on Safety of Medicines in May 1998 that manufactured blood products should not be sourced from UK plasma for the present time.

4. The MSBT membership is as follows:

Dr Pat Troop, Deputy Chief Medical Officer, Department of Health – Chair

Dr A J Cant, Communicable diseases physician, Department of Paediatrics, Newcastle General Hospital

Dr B McClelland, Director, Edinburgh and South East Scotland RTC

Mr J L Forsythe, Consultant Transplant Surgeon, Royal Infirmary of Edinburgh

Dr D W Gorst, Consultant haematologist, Royal Lancaster Infirmary

Professor P MacMaster, Surgeon specialising in liver transplantation, Birmingham

Dr P Mortimer, Virologist, Public Health Laboratory Service

Dr R J Perry, Director, Protein Fractionation Centre, Edinburgh

Dr A Robinson, Medical Director, National Blood Authority

Dr C Dash, Medical Director, Bio Products Laboratory, Elstree

Dr R E Warren, Microbiologist, Director of PHLS laboratory, Shrewsbury

Dr T Wyatt, Consultant clinical scientist, microbiology department, Mater Hospital Trust, Belfast

Professor A J Zuckerman, Virologist, Royal Free and University College Medical School, London

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