# Expanded Criteria Donors: Process and Outcomes

Akinlolu O. Ojo
Department of Medicine, University of Michigan, Ann Arbor, Michigan

**ABSTRACT**

Expanded criteria donor (ECD) kidneys are transplantable deceased donor (DD) kidneys for which the average patient, graft survival, and renal function are inferior when compared to standard criteria DD kidneys. Although the term ECD kidneys has been used since the early 1990s to describe kidneys with various characteristics associated with poorer outcomes, the concept has been formally implemented in U.S. organ allocation. A DD kidney is considered to be an ECD organ if the estimated adjusted risk of graft failure is ≥ 70% (RR ≥ 1.70) compared to DD kidneys with standard characteristics of transplant suitability. The donor characteristics that define an ECD kidney include age ≥ 60 years, or age 50–59 years plus two of the following: cerebrovascular accident as the cause of death, preexisting hypertension, or terminal serum creatinine greater than 1.5 mg/dl. In the aggregate, recipients of ECD kidneys have improved survival compared to end-stage renal disease (ESRD) patients on the kidney transplant waiting list. Patient survival is 5% lower at 1 year and 8–12% lower at 3–5 years for ECD kidney recipients. Adjusted graft survival in ECD kidneys is 8% lower at 1 year and 15–20% lower at 3–5 years after transplantation compared to standard criteria donor kidneys. However, patients less than 40 years of age, African Americans, Asians for whom the median waiting time is less than 1350 days receive no survival benefit from ECD kidney transplantation. Informed choice by the potential recipient is a prominent feature of the allocation policy regarding ECD kidneys. Since there are recipient characteristics associated with no survival benefit following ECD transplantation, nephrologists who refer patients for kidney transplantation should be familiar with the combination of donor and recipient factors that are likely to yield detrimental results.

Among others, the characteristics of a deceased organ donor and the physiologic function of the retrieved organ have a powerful influence on the clinical outcomes of the organ transplantation. Although the criteria used to define a transplantable organ are neither uniform nor consistent, donor-related factors known to be associated with diminished graft and patient outcomes of deceased donor (DD) kidney transplantation are well defined. The presence of greater than 20% globally sclerosed glomeruli on the preimplantation biopsy; a history of donor hypertension, diabetes mellitus, hepatitis B or C, malignant neoplasm, or sepsis in the donor; anatomic abnormalities; extreme donor age; and gross mismatch in donor-recipient weight have been implicated as determinants of inferior outcomes and donor kidneys with these characteristics were often discarded (1–7). By the early 1990s, consequent to the ever worsening shortage of donor kidneys and the relentless expansion of the waiting list, DD kidneys with one or more of the characteristics that used to be the basis for discarding retrieved DD kidneys were being transplanted into patients (6,8–12).

The term "expanded criteria donor" (ECD) was introduced by Kaufman et al. (13) in 1997 to describe transplantable organs that do not meet the criteria for standard donor organs, in preference to the other descriptive terminologies that were in use, such as suboptimal, inferior, or nonstandard donor kidneys. The comparisons of posttransplant outcomes between standard donor criteria and ECD kidneys showed, with little exception, increased risks of primary nonfunction and delayed graft function, and lower graft survival in the ECD kidneys (14–19). Patient survival was similar in the short term, but lower after 5 years or more in the ECD kidneys (18,20–22). The global picture that emerged from the published results of ECD kidney transplantation was that DD kidneys that would have been discarded if there was an abundance of organs were yielding posttransplant results that clearly confer significant, albeit inferior, survival benefits to the recipients, particularly when juxtaposed against the misery, tedium, and short life expectancy associated with maintenance dialysis treatment.

By 1997, 10–15% of DD kidneys transplanted in the United States were ECD kidneys (17,23–25). In an effort to decrease the discarding of ECD kidneys, the Kidney Working Group ("Maximizing the Use of Organs Recovered from the Cadaver Donor," March 28–29, 2001, Crystal City, VA) recommended the development of formal criteria to define the transplanted kidneys that did not meet the standard criteria and called for research to define the interaction between recipient characteristics and nonstandard kidneys with respect to outcomes. Work from the Scientific Registry of Transplant Recipients (SRTR) and published data from single-center studies

*Address correspondence to*: Akinlolu O. Ojo, MD, PhD, Division of Nephrology, University of Michigan Medical Center, 3914 Taubman Center, Box 0364, Ann Arbor, MI 48109-0364, or e-mail: aojo@umich.edu.

*Seminars in Dialysis*—Vol 18, No 6 (November–December) 2005 pp. 463–468

**TABLE 1. Characteristics used to define an expanded criteria donor in the OPTN allocation policy 3.5.1 (allocation of cadaveric donor kidneys) (34)**

| | Donor age categories (years) | | | | |
|---|---|---|---|---|---|
| Donor characteristics | < 10 | 10–39 | 40–49 | 50–59 | ≥ 60 |
| CVA + HTN + creatinine > 1.5 | | | | X | X |
| CVA + HTN | | | | X | X |
| CVA + creatinine > 1.5 | | | | X | X |
| HTN + creatinine > 1.5 | | | | X | X |
| CVA | | | | | X |
| HTN | | | | | X |
| Creatinine > 1.5 | | | | | X |
| None of the above | | | | | X |

The donor must meet the criteria of age ≥ 60 years or age 50–59 years plus two other criteria to be defined as an expanded criteria donor. All other donors who do not fulfill these criteria are described as standard criteria donor or non-ECD.

CVA, cerebrovascular accident as the cause of donor death; HTN, preexisting history of hypertension; creatinine > 1.5, serum creatinine greater than 1.5 mg/dl.

were considered by the Organ Procurement and Transplantation Network (OPTN), which then recommended the codification of ECD kidneys and proposed a revision of the allocation policy to optimize the placement of ECD kidneys (25). In November 2001, the OPTN board approved the definition of ECD (Table 1) and revised the allocation policy to require that, at the time of listing, patients should be given the option of whether or not they wish to considered for an ECD kidney transplant (26).

The allocation policy that became operational in October 2002 (UNOS Policy 3.5, Allocation of Cadaveric Kidneys) states inter alia "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 on time waiting and not the HLA matching. The UNOS Organ Center will attempt to place expanded criteria donor organs for the zero antigen mismatched patients, according to the national list of patients waiting for expanded criteria kidneys for a period of two hours, after which time the UNOS Organ Center will notify the host OPO that it may allocate the expanded criteria kidneys by the standard geographic sequence of local, regional, and national allocation. OPOs are required to identify potential recipients (i.e., perform a match run and start the process of notifying the appropriate transplant program(s) regarding the organ offer) for kidneys they procure from expanded criteria donors within hours post cross-clamp or offer the organs for eligible patients listed regionally and the nationally" (26). Since studies have shown that reluctance to accept ECD kidneys often leads to excessively long cold ischemia time during the placement effort, resulting in a high discard rate of these kidneys (26), the revised allocation policy has two main thrusts: First, a well-defined time limit was imposed on the process of offering the ECD kidney to minimize the cold preservation time, which has been well established as a risk factor for delayed graft function and possibly poorer graft survival (27–29); and second, patient choice was given a prominent role to ensure that transplant candidates are given sufficient information regarding the process of allocation and clinical outcomes of ECD kidneys. An example of the consent document for the ECD option on the waiting list is included in the appendix.

It is important to emphasize that there is no separate waiting list for ECD kidneys and no points are awarded for being willing to receive an ECD kidney (i.e., patients do not advance further on the list based on this choice). Willingness to receive an ECD kidney is simply a recorded option that is open to all waiting list registrants, such that when an ECD kidney becomes available, only those who have recorded a willingness to receive an ECD kidney are included in the match run (the computerized nationwide algorithm based on specified allocation rules that is used to allocate all DD organs). Furthermore, a patient on the waiting list may change their ECD kidney option at anytime. As of July 2003, 43% of patients on the waiting list for kidney transplantation indicated that they would consider an ECD kidney offer (30,31). In 20–30% of donation service areas (geographic units served by an individual organ procurement organization), 80–100% of patients on the list were willing to receive an ECD kidney transplant (30).

## Characteristics of ECD Kidneys

By definition, an ECD kidney results in inferior clinical outcomes compared to standard criteria donor kidney. In a broad sense, numerous donor-related attributes associated with inferior graft results have been used to define an ECD kidney: risk of infectious disease or malignancy transmission, donor hypertension or diabetes mellitus, donor death due to thrombo-occlusive cerebrovascular accident, donor mechanism of death (cardiac death versus brain death), anatomic vascular abnormalities and histomorphology, donor age greater than 60 years, donor age less than 10 years, elevated terminal serum creatinine levels, or a history of high-risk behavior.

Although implementation of the ECD option in the OPTN allocation policy is based on a limited number of simple, easily measurable characteristics (Table 1), any number of criteria outside the OPTN policy continue to be used to define ECD kidneys by researchers and clinicians. When the term ECD kidney is used, it is always useful to provide the context of whether the definition is based on the description in the OPTN allocation or whether the term includes other criteria. For example, it is important to distinguish an ECD kidney from a kidney that is procured after cardiac death. Donation after cardiac death (DCD) is defined as organ donation obtained after the deceased suffered cardiac arrest, in contrast to the standard approach in which organ retrieval occurred after primary brain death while cardiovascular function is maintained. A DCD kidney may still qualify as an ECD kidney if the criteria in Table 1 are met. However, in practice, DCD kidneys are often broadly described as ECD kidneys.

**TABLE 2. Patient and renal allograft survival in ECD and standard criteria donor kidneys from 3 months to 5 years posttransplant (34)**

| | Patient survival | | Allograft survival | |
|---|---|---|---|---|
| Survival time | Expanded criteria donor (%) | Standard criteria donor (%) | Expanded criteria donor (%) | Standard criteria donor (%) |
| 3 months | 96.0 | 97.5 | 90.4 | 94.0 |
| 1 year | 90.6 | 94.5 | 81.7 | 89.3 |
| 3 years | 78.5 | 89.9 | 65.1 | 80.4 |
| 5 years | 69.9 | 81.2 | 48.6 | 65.2 |

## Outcomes Following ECD Kidney Transplantation

Kidney transplantation enhances quality of life and improves patient survival in all patient groups (32,33). However, the survival benefits seen in recipients of ECD kidney transplants are inferior compared to recipients of standard criteria donor kidneys. Using OPTN/SRTR data, Danovitch et al. (23) reported that the annual death rate for recipients of ECD kidneys was 100/1000 patient-years at risk compared to 48/1000 patient-years at risks for recipients of standard criteria kidneys. The adjusted patient survival at 1 and 5 years for ECD kidneys was 90.6% and 69.9%, compared to 94.5% and 81.2% for non-ECD (or standard criteria donor) kidneys, respectively (34). Table 2 shows the survival rates for ECD and non-ECD kidneys based on OPTN/SRTR, as reported by Metzger et al. (34). Single-center studies are in general agreement with registry data with respect to the inferior survival seen with ECD kidneys, with a few exceptions (20). On average, patient survival is 5% lower at 1 year and 8–12% lower at 3–5 years for ECD kidney recipients (23,34). Considered in another way, the projected added-life years following a standard criteria donor kidney is 10 years versus 5.1 years for ECD kidneys (33,35). Other recipient characteristics such as age and race are associated with more or less likelihood of survival benefit following ECD kidney transplantation.

The finding of improved longevity with ECD kidney transplantation relative to waiting lists is not a very realistic comparison, as recipients who turn down the offer for an ECD kidney are typically highly placed on the waiting list and thus are likely to receive a standard criteria donor kidney shortly thereafter. The ideal comparison in which ECD kidney transplant is compared with the integral of the short additional waiting time and receipt of a standard criteria donor kidney has not yet been published.

The indices of renal allograft performance, such as delayed graft function, acute rejection, and allograft survival, are also often inferior in ECD transplants. In a comparison of 37 ECD kidneys versus 53 standard criteria donor kidneys, Stratta et al. (19) found no difference between ECD and standard criteria donor kidney transplant recipients in the risk of delayed graft function (21% versus 11%, $p = 0.26$), acute rejection (13.5% versus 15%, $p$ = NS), days to serum creatinine less than 3.0 mg/dl ($8.3 \pm 10.7$ versus $8.2 \pm 11.4$, $p$ = NS), and graft survival after 16 months (86.5% versus 89%, $p$ = NS). However, estimated creatinine clearance was significantly lower in the ECD kidneys (67 ml/min versus 94 ml/min, $p < 0.001$) (19). In a retrospective analysis of 582 DD transplants, Keitel et al. (20) found no difference between ECD and non-ECD kidneys in the rates of acute rejection (66.1% versus 72.3%, $p = 203$) and graft survival at 1 and 5 years (74% versus 82% and 57% versus 59%, $p = 0.207$).

Notwithstanding these reports, large studies and analysis from transplant registries show significantly inferior graft survival results for ECD kidneys when compared to standard criteria donor kidneys (Table 2). On average, the adjusted graft survival in ECD kidneys is 8% lower at 1 year and 15–20% lower at 3–5 years after transplantation compared to standard criteria donor kidneys (23,34,36).

## Impact of Recipient Characteristics on ECD Kidney Transplantation

The survival benefits of kidney transplantation are strongly modified by recipient-based factors. Although the overall survival in recipients of ECD kidneys is significantly better than wait-listed dialysis patients, some patient groups have been shown to receive no improvement in patient survival following an ECD kidney transplant (31). In patients with a waiting time of less than 1350 days, an ECD kidney resulted in no survival benefit for patients older than 40 years, African Americans, or Asians (31). Therefore nephrologists should be mindful of recommending an ECD kidney to their patients who meet these demographic criteria if the average waiting time is less than 1350 days in their donation service area.

Apart from waiting time, recipient age, race, and cause of end-stage renal disease (ESRD) may also modify the magnitude of the clinical benefits from an ECD donor transplant. Ojo et al. (37) reported a projected increase in life span of 7.3 years in recipients of marginal donor kidney transplants for patients age 55–64 years at the time of kidney transplantation, whereas the corresponding additional life span was decreased to 3.8 years in recipients who were 65 years or older. Metzger et al. (34) found a 5-year patient survival of 69.0%, 71.7%, and 80.3% in white, African American, and Asian ECD recipients, respectively. The impact of these demographic characteristics on patient survival after receiving a standard criteria donor kidney transplant is not as large.

## Trends Since Implementation of OPTN Allocation Policy 3.5.1 (ECD Kidneys)

One of the goals of the revised allocation policy for ECD kidneys was to expedite the placement of these

kidneys so that organ discard rates would be reduced. It was anticipated that informed patient choice would enhance the rate of procurement and expeditious disposition of the "kidneys that nobody wanted." In 2003, the number of ECD kidneys recovered increased by 18%, compared to a 1% increase for standard criteria donor kidneys (37). This increase accounted for most of the 7.7% increase in DD transplants performed in the United States compared to the previous year (31). The mean number of kidneys transplanted from ECD donors was 1.24, compared to 1.78 for non-ECD kidneys in donors less than 60 years of age.

Expeditious placement of ECD kidneys seems to have been realized even though the change in policy is relatively new. The number of ECD kidneys transplanted with a cold ischemia time of less than 12 hours increased from 10% in 2001 to 17% in 2003 (23). By mid-2003, almost half (43%) of all waiting list registrants indicated a willingness to accept an ECD kidney. Since the allocation of an ECD kidney does not include points for human leukocyte antigen (HLA) mismatch, except zero antigen mismatch, the majority (52%) of ECD transplants were highly mismatched (five to six HLA mismatches), which represents a 40% increase in high grade HLA mismatched transplants since the introduction of the new policy (23).

## Future Directions

Optimal utilization of ECD has not been fully realized. Only a small group of recipients have been shown to be less likely to benefit from receiving an ECD kidney transplant. Judging the survival benefits of ECD kidney transplantation against maintenance dialysis therapy is not the ideal comparison. Thus the decision as to which candidates are most suitable for ECD kidney transplantation and whether there are additional groups of patients for whom an ECD kidney constitutes a prohibitive risk currently rely on an incomplete ascertainment of benefits. In particular, there are no published studies in which the survival benefits of ECD transplants have been evaluated against the outcomes in patients who declined ECD transplant and subsequently received a non-ECD transplant. Resolving these types of issues requires additional time and experience with the new allocation policy and the development of appropriate statistical analytic techniques.

Second, the current definition of an ECD kidney, while simple to utilize, omits important donor-based prognostic indicators. Histomorphologic kidney data, donor-recipient weight ratio, and donor age less than 10 years were not included in the current definition. It is therefore highly likely that the current definition of ECD kidneys and allocation policy will continue to undergo modifications as additional data become available on more donor-related factors and the impact of their interactions with recipient characteristics on posttransplant patient and allograft results.

## Conclusion

Expanded criteria donor kidney transplantation has introduced a new dimension to the process and outcomes of kidney transplantation. By definition, recipients transplanted with an ECD kidney have inferior graft and patient survival results. Five-year graft and patient survival are 15–20% and 8–13% lower, respectively, for ECD kidneys. ECD kidneys account for 15–20% of DD kidneys currently transplanted in the United States. Most of the growth in DD transplantation now comes from these ECD kidneys.

To date, only patients less than 40 years of age, African American, or Asian listed in organ procurement organization (OPOs) with median waiting times of less than 1350 days are known not to be well served by receiving ECD kidney transplants, as they stand to derive no clinical benefits in terms of patient and graft survival. The new allocation policy has lessened the overall frequency of discarding kidneys and shortened the cold ischemia time for ECD kidney transplantation. Evolutionary changes in the current policy will be necessary as more is learned about additional donor factors and recipient characteristics that impact the outcome of ECD kidney transplantation. Practicing nephrologists need to be more familiar with the definition of ECD kidneys, the associated transplant results, and the basic operations of the allocation policy so that they can effectively counsel their patients on whether to exercise the option for an ECD kidney (at the time of registration for the waiting list) and assist patients in making an informed decision when an ECD kidney offer materializes.

## References


1. Cecka JM, Cook DJ: Optimal use of cadaver donor kidneys: high-risk donors and low-risk recipients. *Transplant Proc* 21:1417–1418, 1989
2. O'Connor KJ, Bradley JW, Cho SI: Extreme donor age in kidney transplantation. *Transplant Proc* 20:770–771, 1988
3. Sugiyama S, Tsuyuki M, Okazaki Y, Takeuchi N, Matsuura O, Ohshima S: Arteriosclerotic lesions of donor kidney and graft survival. *Transplant Proc* 26:929–930, 1994
4. Jordan ML, Shapiro R, Vivas CA, Scantlebury VP, Corry RJ, Randhawa P, Hakala TR, Starzl TE: High-risk donors: Expanding donor criteria. *Transplant Proc* 31:1401–1403, 1999
5. Smith RB, Fairchild R, Bradley JW, Cho SI: Cadaver kidney donors with hypertensive histories. *Transplant Proc* 20:741–742, 1988
6. Golconda MS, Whiting JF, Smith R, Hayes R, Alexander JW, First MR: Long-term outcome of kidney transplantation from expanded criteria donors: a single center experience. *Transplant Proc* 29:3379–3381, 1997
7. Feduska NJ Jr, Cecka JM: Donor factors. *Clin Transplant* 8:381–394, 1994
8. Rosenthal JT, Misertino DP, Mendez R, Koyle MA: Extending the criteria for cadaver kidney donors. *Transplant Proc* 22:338–339, 1990
9. Alexander JW, Vaughn WK, Carey MA: The use of marginal donors for organ transplantation: the older and younger donors. *Transplant Proc* 23:905–909, 1991
10. Plotkin JS, Ridge L, Kuo PC, Lim J, Njoku MJ, Johnson LB: Extending the boundaries of acceptable organ donors: a means of expanding the donor pool for liver transplantation. *Transplant Proc* 29:3288, 1997
11. Ratner LE, Kraus E, Magnuson T, Bender JS: Transplantation of kidneys from expanded criteria donors. *Surgery* 119:372–377, 1996
12. Kauffman HM, McBride MA, Rosendale JD, Ellison MD, Daily OP, Wolf JS: Trends in organ donation, recovery and disposition: UNOS data for 1988–1996. *Transplant Proc* 29:3303–3304, 1997
13. Kauffman HM, Bennett LE, McBride MA, Ellison MD: The expanded donor. *Transplant Rev* 11:165–190, 1997
14. Mascaretti L, Pappalettera M, Gravame V, Chiecca R, Scalamogna M, Sirchia G: Cadaver kidney transplantation using donors with hypertension in the north Italy transplant program. *Transplant Proc* 22:382, 1990
15. Vivas CA, O'Donovan RM, Jordan ML, Hickey DP, Hrebinko R, Shapiro R, Starzl TE, Hakala TR: Cadaveric renal transplantation using kidneys from donors greater than 60 years old. *Clin Transplant* 6:77–80, 1992
16. Whiting JF: Clinical and economic outcomes of the use of expanded criteria donors in renal transplantation. *Semin Dial* 13:316–319, 2000
17. Lee CM, Scandling JD, Shen GK, Salvatierra O, Dafoe DC, Alfrey EJ: The kidneys that nobody wanted: support for the utilization of expanded criteria donors. *Transplantation* 62:1832–1841, 1996

18. Golconda MS, Whiting JF, Smith R, Hayes R, Alexander JW, First MR: Long-term outcome of kidney transplantation from expanded criteria donors: a single center experience. *Transplant Proc* 29:3379–3381, 1997
19. Stratta RJ, Rohr MS, Sundberg AK, Armstrong G, Hairston G, Hartmann E, Farney AC, Roskopf J, Iskandar SS, Adams PL: Increased kidney transplantation utilizing expanded criteria deceased organ donors with results comparable to standard criteria donor transplant. *Ann Surg* 239:688–695, 2004; discussion 95–97
20. Keitel E, Michelon T, dos Santos AF, Bittar AE, Goldani JC, D'almeida Bianco P, Bruno RM, Losekann A, Messias AA, Bender D, Bianchini JJ, Duro Garcia V: Renal transplants using expanded cadaver donor criteria. *Ann Transplant* 9(2):23–24, 2004
21. Lee CM, Carter JT, Weinstein RJ, Pease HM, Scandling JD, Pavalakis M, Dafoe DC, Alfrey EJ: Dual kidney transplantation: older donors for older recipients. *J Am Coll Surg* 189:82–91, 1999; discussion 91–92
22. Tan JC, Alfrey EJ, Dafoe DC, Millan MT, Scandling JD: Dual-kidney transplantation with organs from expanded criteria donors: a long-term follow-up. *Transplantation* 78:692–696, 2004
23. Danovitch GM, Cohen DJ, Weir MR, Stock PG, Bennett WM, Christensen LL, Sung RS: Current status of kidney and pancreas transplantation in the United States, 1994–2003. *Am J Transplant* 5(4 pt 2):904–915, 2005
24. Mandal AK, Kalligonis AN, Ratner LE: Expanded criteria donors: attempts to increase the renal transplant donor pool. *Adv Ren Replace Ther* 7:117–130, 2000
25. Gaston RS, Danovitch GM, Adams PL, Wynn JJ, Merion RM, Deierhoi MH, Metzger RA, Cecka JM, Harmon WE, Leichtman AB, Spital A, Blumberg E, Herzog CA, Wolfe RA, Tyan DB, Roberts J, Rohrer R, Port FK, Delmonico FL: The report of a national conference on the wait list for kidney transplantation. *Am J Transplant* 2003;3:775–785
26. Rosengard BR, Feng S, Alfrey EJ, Zaroff JG, Emond JC, Henry ML, Garrity ER, Roberts JP, Wynn JJ, Metzger RA, Freeman RB, Port FK, Merion RM, Love RB, Busuttil RW, Delmonico FL: Report of the Crystal City meeting to maximize the use of organs recovered from the cadaver donor. *Am J Transplant* 2:701–711, 2002
27. Troppmann C, Gillingham KJ, Gruessner RWG, Dunn DL, Payne WD, Najarian JS, Matas AJ: Delayed graft function in the absence of rejection has no long-term impact. A study of cadaver kidney transplant recipients with good graft function at 1 year after transplantation. *Transplantation* 61:1331–1337, 1996
28. Ojo AO, Wolfe RA, Held PJ, Port FK, Schmouder RL: Delayed graft function: risk factors and implications for renal allograft survival [see comments]. *Transplantation* 63:968–974, 1997
29. Yokoyama I, Uchida K, Kobayashi T, Tominaga Y, Orihara A, Takagi H: Effect of prolonged delayed graft function on long-term graft outcome in cadaveric kidney transplantation. *Clin Transplant* 8(2 pt 1):101–106, 1994
30. Sung RS, Guidinger MK, Leichtman AB: Initial experience with the expanded criteria donor kidney allocation system: impact on utilization [abstract]. *Am J Transplant* 4(suppl 8):303, 2004
31. Crippin JS: What's new–what's hot in clinical science: American Transplant Congress 2004. *Am J Transplant* 4:1747–1753, 2004
32. Schnitzler MA, Whiting JF, Brennan DC, Lin G, Chapman W, Lowell J, Boxerman S, Hardinger KL, Kalo Z: The expanded criteria donor dilemma in cadaveric renal transplantation. *Transplantation* 75:1940–1945, 2003
33. Wolfe RA, Ashby VB, Milford EL, Ojo AO, Ettenger RE, Agodoa LY, Held PJ, Port FK: Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant [see comments]. *N Engl J Med* 341:1725–1730, 1999
34. Metzger RA, Delmonico FL, Feng S, Port FK, Wynn JJ, Merion RM: Expanded criteria donors for kidney transplantation. *Am J Transplant* 3(suppl 4):114–125, 2003
35. Ojo AO, Hanson JA, Meier-Kriesche H, Okechukwu CN, Wolfe RA, Leichtman AB, Agodoa LY, Kaplan B, Port FK: Survival in recipients of marginal cadaveric donor kidneys compared with other recipients and wait-listed transplant candidates. *J Am Soc Nephrol* 12:589–597, 2001
36. Ojo AO, Leichtman AB, Punch JD, Hanson JA, Dickinson DM, Wolfe RA, Port FK, Agodoa LY: Impact of pre-existing donor hypertension and diabetes mellitus on cadaveric renal transplant outcomes. *Am J Kidney Dis* 36:153–159, 2000
37. Delmonico FL, Sheehy E, Marks WH, Baliga P, McGowan JJ, Magee JC: Organ donation and utilization in the United States, 2004. *Am J Transplant* 5(4 pt 2):862–873, 2005

## Appendix: Sample Informed Consent for Acceptance of Expanded Criteria Donor Kidneys (34)

**Introduction**

We invite you to take part in a program to better use kidneys recovered from donors with conditions that make it more difficult to efficiently place them for transplantation. Please take your time to make your decision. Discuss it with your family and friends and feel free to ask us questions also. This program will not be recommended for all of our patients. It is important that you read this document and understand several general principles that apply to all who take part in our expanded criteria donor program.

This program has been developed by the Organ Procurement and Transplantation Network, the organization that manages the national patient waiting list.

This program does not replace the waiting list already in place; it simply offers a means for some patients to receive a transplant more quickly.

Taking part in this program is entirely voluntary.

Those participating in the program will still be participating in the regular waiting list program for the kidneys distributed through that listing.

You may withdraw from the program at any time without incurring any penalties or loss of waiting time points.

You are urged to ask any questions you have about this program of the staff members who explain it to you.

**Why is this program being offered?**

There is a serious shortage of cadaver kidneys (kidneys recovered from someone who died) while, at the same time, transplantation is beneficial to an increasing number of patients with kidney failure. The waiting list increases by several thousand each year and more than 4000 patients will die waiting for a kidney transplant this year. The waiting time for a cadaver kidney is more than 4 years in most parts of the country. Many patients are waiting longer because their transplant markers, which determine a kidney match, may not be very common and keep them from having enough points to get a kidney offer.

One way to increase the number of cadaver kidneys is to use "expanded criteria" donors; these are donors who are older or who have specific health problems that might affect how well and how long their kidneys will work after they

are transplanted. Many of these kidneys are already being transplanted, but a large number are discarded when the time to get them transplanted is too long, resulting in too much damage. This new program will allow transplant centers to use them locally without having to go entirely through the national system. We believe this will help those kidneys to perform better and provide adequate function for the recipients to stop dialysis. A study done by the national kidney program showed that patients receiving these kidneys add about 5 extra years to their life compared to not receiving a transplant and remaining on dialysis.

You are being told about this program because you have kidney failure, you do not have a potential living kidney donor, and, given your age and overall condition, you might receive significant benefit from an expanded criteria donor kidney.

**What is involved in the program?**
To take part in the program, you will be asked to sign this informed consent document. Kidneys from expanded criteria donors will be offered only to patients who have agreed in advance to be considered for them. They will be offered first to anyone on this list who is a perfect match. If there is no perfect match, then they will be offered to the compatible patient waiting the longest on the list. The kidneys from donors who meet the following criteria will be placed by this program. All donors 60 or older are considered expanded criteria donors and all donors between the ages of 50 and 59 who have two or more of the following: (1) the donor died from a stroke or cerebrovascular accident; (2) the donor had a medical history of hypertension (high blood pressure); and/or (3) the donor's most recent creatinine was 1.5 mg/dl or greater (creatinine is a measure of how well the kidney works; normal values typically range from 0.6 to 1.2 mg/dl).

You will have all the medical tests and procedures that are part of the regular recipient medical examination if you do or do not enroll in this program. You may require more frequent biopsies of the transplanted kidney to assess for kidney function and potential rejection episodes after the transplant. You may require dialysis for a short period of time after the transplant. Long-term kidney function may be less than that from a nonexpanded criteria donor kidney.

**Are there any benefits to taking part in this program?**
The main benefit would be to shorten the time you wait for a kidney transplant. Recent analysis of transplant data showed that the longer you wait on dialysis for a transplant, the poorer the transplant outcome.

**What other options are there?**
Remember, you will still be listed on the regular waiting list for a nonexpanded donor kidney. You may also decline to enroll in this program. Your other option would be a living donor transplant from a family member, a friend, or even a willing stranger.

**What are the costs?**
You or your insurance company will be charged for the continuing medical care and/or hospitalization that are part of the kidney transplant procedure. There are no additional or special costs that are part of the expanded criteria kidney donor program.

**What are my rights as a participant?**
Taking part in this program is voluntary. You may choose not to take part in or leave the program at any time. If so, your regular care will not be affected and you will not lose any of the benefits you would normally receive. We will try to keep you informed of any new developments pertaining to this program.

**Who do I call if I have any questions or problems?**
For question about the program, contact your pretransplant coordinator _____; or your transplant physician _____.

**Signatures**
As a representative of this program, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this program. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____
Signature of person obtaining the consent Date

I, the undersigned, have been informed about this program's purpose, procedures, possible benefits and risks, and I have received a copy of this consent document. I have been given the opportunity to ask questions and I have been told I can ask questions in the future. I voluntarily agree _____ or do not agree _____ (initial appropriately) to participate in this program. I am free to withdraw from the program at any time without need to justify my decision. A withdrawal will not in any way affect my future treatment or medical management.

_____ _____
Signature of person obtaining the consent Date