

Meeting Report

The Report of a National Conference on the Wait List for Kidney Transplantation

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In March, 2002, over 100 members of the transplant community assembled in Philadelphia for a meeting designed to address problems associated with the growing number of patients seeking kidney transplantation and added to the waiting list each year. The meeting included representatives of nine US organizations with interests in these issues. Participants divided into work groups addressing access to the waiting list, assigning priority on the list, list management, and identifying appropriate candidates for expanded criteria donor kidneys. Each work group outlined problems and potential remedies within each area. This report summarized the issues and recommendations regarding the waiting list for kidney transplantation addressed in the Philadelphia meeting.

Key words: Access, kidney transplant, minority, waiting list, wait list management

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Introduction

On 4–5 March 2002, members of the transplant community held a national conference in Philadelphia, PA to address the expanding list of candidates awaiting kidney transplantation. Participants included representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the Scientific Registry of Transplant Recipients (SRTR), the Association of Organ Procurement Organizations (AOPO), the United Network for Organ Sharing (UNOS), the National Institute

of Health (NIH), the American Society for Histocompatibility and Immunogenetics (ASHI), the Division of Transplantation of the Department of Health and Human Services (DOT), and the National Kidney Foundation (NKF). The meeting was sponsored by the AST, ASTS, DOT, and the NKF.

Between 1990 and mid-2002 the kidney transplant waiting list has grown from approximately 15 000 patients to 55 000 patients, while the number of cadaveric kidneys transplanted annually remained stable at approximately 9000 (1). As a result, the median waiting time between listing and transplantation has increased from 19 months (as of a decade ago) to more than 3 years for those listed in 1999 (2). It is projected that by the year 2010, the waiting list will have 100 000 patients and the average waiting time will be nearly 10 years (3). Waiting lists are also burgeoning at individual centers, with some maintaining registries of 500–1500 patients ready to receive a transplant (4).

The goal of the conference was to review national policies affecting the wait list for kidney transplantation, identify problems in their clinical implementation, and suggest remedies to facilitate the process. A focus of the conference was to address the special problems faced by minorities. There were four work groups and each was assigned a specific topic to consider: access to the waiting list, assigning priority on the list, management of the list, and identifying appropriate recipients for expanded criteria donor kidneys.

Work Group 1: Access to the Waiting List

Kidney transplantation is the treatment of choice for most patients with end-stage renal disease (ESRD) (5). Transplantation requires access to the waiting list. This work group evaluated the process leading to wait-listing, attempted to define impediments in its implementation, and advanced recommendations regarding potential remedies. The group unanimously endorsed a goal of fair and equitable access to kidney transplantation for all patients with ESRD, via a process whose workings are transparent to all.

This Work Group assumed that access to the waiting list could only occur via access to a transplant center. Referral of potential recipients should result in timely completion of

the evaluation process and, if acceptable, kidney transplantation from a live donor or wait-listing for a cadaver organ. However, the group acknowledged that, while access to a transplant center and the waiting list is necessary, it may not always ensure access to transplantation.

Why promote accessibility to a list that already exceeds the supply of donated organs (2)? On the contrary, the work group thought any other approach would be grossly unfair to newly diagnosed ESRD patients, as well as those excluded from a more limited process.

Access to the transplant center: the current process

Optimal outcomes occur when kidney transplantation is performed as early as possible after onset of ESRD (6). Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines recommend early referral of those with chronic kidney disease (CKD) to a nephrologist (7). Nevertheless, current data indicate that most CKD patients do not see a nephrologist until very late in the course of their renal disease, making preemptive transplantation an option for only a small fraction of CKD patients (8–10). After the onset of ESRD, dialysis staff (with widely variable knowledge regarding transplantation) become the primary source of information for many patients and thus, to some degree, the gatekeepers for transplantation. Even after referral to a transplant center, months may elapse before the initial visit. When educated about transplantation as a therapeutic option, most patients desire referral to a transplant center (11). Unfortunately, much of an ESRD patient's education about transplantation now occurs only after initiation of the evaluation process. For most patients, evaluation means several outpatient visits for interviews and testing to determine eligibility for transplantation. Finally, transplant center personnel review accumulated results, and arrive at a decision regarding a patient's suitability for transplantation.

Barriers in access to transplantation

Is there equal access to the waiting list for all qualified ESRD patients? The Access Work Group concluded that the answer is no, and listed several known impediments to wait listing (Table 1) (11–18). More specifically, additional, potentially modifiable, barriers to access may exist

Table 1: Documented variables that may inhibit timely referral for transplantation

- Lower level of educational attainment
- Lower socioeconomic status
- Non-English-speaking background
- Minority race
- Female gender
- Dialysis in for-profit or isolated units
- Certain medical diagnoses such as diabetes mellitus
- Obesity

(References 11-18)

at multiple steps in the process, involving patients (14,19), dialysis providers (11,20–23), and transplant centers (19,24).

For patients: Accurate information regarding transplantation is not widely available early in the course of CKD. Some actually receive false information. Newly diagnosed patients may be fearful and mistrusting of the 'system', still struggling with the recent burden of chronic illness and dialysis. Even after referral, many ESRD patients are unable to deal with the additional financial, physical, and emotional demands of transplant evaluation, especially when the process includes nonreimbursed expenses and travel (19). There is also concern about the cost of expensive medications and the loss of Medicare disability benefits after transplantation (20).

Among dialysis providers: In a busy dialysis unit, there is often little time for teaching patients about transplantation. In addition, dialysis professionals may have limited knowledge regarding state-of-the-art advances in transplantation, such as expanding utilization of live donors and extended-criteria cadaver donors (21,22). This may result in under-informed or misinformed patients who do not seek referral for transplantation (11). Recent data accumulated by the Inspector General indicate that only 2 of 5 major dialysis providers include referral for transplantation and/or transplantation rates as parameters for continuous quality initiative (CQI) analysis (23).

For the community nephrologist, there are also significant financial disincentives to referral for transplantation and potential conflicts of interest. Reimbursement is poor or nonexistent for counseling or evaluating potential transplant candidates, and referral may result in loss of revenue if the patient is transplanted.

At transplant centers: The approximate number of donor and recipient evaluations performed annually in the United States has grown from 20 000 in 1992 to 34 000 in 2001 (2). Increasing referrals strain the limited resources and personnel available for the evaluation process. Within broad national guidelines, each transplant center defines its own criteria for wait-listing. Because these criteria are often vague and not widely disseminated among referring nephrologists, the system becomes clogged with inappropriate referrals, increasing delays for appropriate ones. Transplant centers often do not adequately coordinate the evaluation process with patients and referring nephrologists. What information is required to initiate evaluation? If a cardiac stress test is required, who is responsible for scheduling and follow-up, the patient, the nephrologist, or the transplant center? Funding for evaluation varies according to the patient and insurance mix at each institution. For many centers, evaluation without prompt transplantation (a growing reality given the size of the waiting list) means outlay of money for tests and consultations that is not quickly reimbursed. This may represent another disincentive to promotion of early referrals (24).

Barriers for minorities: The barriers to transplantation appear greater among minority populations. Black and Native American ESRD patients are more likely than other groups to enter the healthcare system at a more advanced stage of renal failure, with less understanding of transplantation (25). They experience lower referral rates to transplant centers (even among those who express a preference for transplantation), fewer completed evaluations, and fewer become candidates after medical or psychological screening than majority patients (11,14,18,26). Moreover, previously defined barriers to transplantation in minority patients (including HLA matching, presensitization, obesity, and socioeconomic factors) fail to account for the discrepancy in access compared to Caucasian and Asian patients. This gap raised considerable discussion at the Conference as to whether ethnic prejudices may impede access to transplantation.

Improving access to the waiting list (Table 2)

Remedies for patients:

1 Improved education: To increase the probability of early transplantation, patient education must occur *early* in the course of CKD (8). Community teaching about transplantation should be incorporated into the new National Institutes of Health initiative, the National Kidney Disease Education Program (27) with the goal of providing accurate information sufficient to dispel myths about transplantation (positive and negative). Educational programs in dialysis units should be comprehensive, understandable, standardized, and mandatory. To be effective, such programs will likely require the input of transplant professionals thoroughly familiar with the evaluation process and criteria for wait-listing. Current Medicare statutes provide funding for transplant centers to initiate such programs. (see below)

2 Greater autonomy: In the absence of clear contraindications, ESRD patients should be offered the option

of transplantation; those who choose it should be referred to a transplant center. Patients should be allowed to fill out their own Center for Medicare Services (CMS) forms regarding their wishes about transplantation. When patients decline transplantation, these forms should provide evidence, perhaps in the form of self-specification, that the patient understands why he or she is/is not a transplant candidate.

3 Easy access to local transplant center: Insurance contracting that requires patients to bypass local centers in favor of distant ones should be discouraged. At a minimum, travel and living support should be provided during the evaluation process.

4 Immunosuppressive medication coverage for the life of the allograft: Because the high cost of immunosuppressive drugs may discourage ESRD patients from seeking transplantation, equitable access to the waiting list is possible only if this disincentive is minimized.

Remedies for dialysis providers: Nephrologists and other dialysis professionals must play a greater role in encouraging transplantation among ESRD patients.

1 Documentation: The ESRD Medical Evidence Report (CMS Form 2728) should require documentation that adequate education *and* information regarding referral for transplantation have been provided and this documentation must be shown for *all* ESRD patients. Were the patients referred to a transplant center and at what level of renal impairment? If a patient is deemed not acceptable for transplantation, why not?

2 Feedback: CMS reports to dialysis providers and the 'Dialysis Facility Compare' feature of www.Medicare.gov should include comparative referral, wait list, and transplant rates at individual centers; provider networks should utilize these data as CQI parameters.

Table 2: Proposed remedies to address barriers in access to transplantation (Work Group 1)

For patients

- Better and earlier access to appropriate information regarding transplantation
- Greater autonomy in determining candidacy for transplantation
- Better support in dealing with logistics of evaluation and transplantation
- Access to immunosuppressive medications for the life of the allograft

For dialysis providers

- Documentation of transplant education and referral
- Improved feedback regarding transplant referral and outcomes
- Transplant center as final arbiter of transplant candidacy
- Increased reimbursement for pretransplant counseling and post-transplant care

For transplant centers

- Increased role in educating patients, dialysis providers, and the community
- Define, promulgate, and apply clear criteria for transplant candidacy
- Greater responsibility in ensuring timely completion of transplant evaluation
- Added funding to institute these efforts

For minorities

- Culturally sensitive education by ethnically similar educators

3 Determination of transplant candidacy: In the absence of well-defined contraindications, the final determination of transplant candidacy should always be made by the transplant center, not the referring nephrologist or health insurance provider.

4 Reimbursement for pretransplant counseling and post-transplant care: Time spent by dialysis providers must be compensated. The increased complexity of managing transplant recipients should be matched by appropriately increased reimbursement to the practitioner, perhaps through a small surcharge to current billing codes for recipients of kidney transplants.

Remedies for transplant centers:

1 Added educational responsibility: Transplant centers must play a greater role in educating patients, dialysis providers, and the community. Funding for additional coordinators whose primary function is to educate dialysis staff is already available under current Medicare statutes. Legislation introduced in the last Congress (HR 3770 and S 2218, the Kidney Disease Educational Benefits Act of 2002) and hopefully to be readdressed in the next session, may provide funding for teaching in primary care and community settings.

2 Greater efficiency in the evaluation process: Transplant centers must define and promulgate widely agreed upon criteria for transplant candidacy. The transplant center is responsible for ensuring that required interviews and studies are scheduled and completed in a timely fashion. Additional funding will be necessary for transplant staff to handle the projected increased number of referrals.

Remedies for minority patients: Beyond implementing the above recommendations, more specific remedies may be required to improve access for minority patients. Education of those with advanced CKD should be culturally sensitive. Recognizing ethnic differences in communications, such education programs should include ethnically similar educators. The Minority Organ and Tissue Transplantation Education Program (MOTTEP) has effectively communicated needs for organ donation to African Americans and is a model for culturally sensitive education regarding the value of renal transplantation.

Work Group 2: Assigning Priority on the List

A major issue considered by the Assigning Priority Work Group was the ethical dilemma posed by allocating kidneys to wait-listed patients in the context of the competing goals of equity and utility. Not only does transplantation offer the long-appreciated benefit of improved quality of life relative to dialysis, it is now clear that successful transplants save lives (5). Given the imbalance between demand and supply of cadaver kidneys, the current allocation system functions as a rationing mechanism. Preferential allocation of kidneys to patients projected

to enjoy a survival benefit following transplantation has not been seriously considered until now. The survival benefit of renal transplantation is quantitatively less than accompanies heart or liver transplantation, because dialysis can maintain life (albeit with shorter life expectancy).

The Assigning Priority Work Group recommended that the criterion of outcome (as determined by patient survival) not be used as a measure of allocation, nor did it support its use in determining access to transplant evaluation and the waiting list.

The utility of HLA matching and equity of kidney offers

The utility of mandatory national sharing of zero ABDR mismatched transplants is currently undisputed, with its benefits on long-term graft survival well documented and accepted as adequate compensation for any negative effects on equity issues such as waiting time (28). However, there was significant criticism of applying lesser degrees of HLA matching to influence recipient selection. This approach has the unintentional consequence of diverting kidneys from those candidates who have waited lengthy periods of time to others listed much later but less difficult to match, an impact disproportionately borne by minority patients. Thus, a goal of the conference was to generate practices that might improve fairness to minorities, without compromising the outcome benefit of HLA matching.

Awarding points for donor/recipient matching at the HLA A locus has already been eliminated from the waiting list allocation algorithm (UNOS policy 3.5.11.2). At the Conference, representatives of the SRTR presented data regarding the influence of matching at the B locus on outcomes. For patients transplanted since 1995, B locus matching did not significantly influence risk of graft failure: two B locus mismatches increased the relative risk of graft loss by 7% over zero B locus mismatches, and one B locus mismatch was associated with the same risk of graft loss as zero B locus mismatch. These data support a currently proposed modification that would delete B locus mismatching from the UNOS sharing algorithm. Under the new proposal, mismatching for Class II antigens at the DR locus would become the principal HLA determinant of kidney allocation, commensurate with its strong influence on graft survival (Table 3). SRTR analysis indicates that such a change would increase kidney allocation to minorities by about 8%, while increasing overall risk of graft failure by only 2% (29). This translates into a very minor reduction in one-year graft survival from 87.3% to 87.0%, and would reduce the disadvantage in access to kidney transplantation currently experienced by minority kidney transplant candidates.

Other remedies to improve equity

The Assigning Priority Work Group recommended the following proposals to improve equity for patients on the wait list:

Table 3: Current¹ and proposed² UNOS point systems for cadaver kidney allocation

Variable	Current (points)	Proposed (points)
Time of waiting	(1) point for each year waiting (+ fractional points assigned on each list)	Same
Quality of antigen mismatch	0 B/DR mismatch (7) 1 B/DR mismatch (5) 2 B/DR mismatch (2)	0 DR mismatch (2) 1 DR mismatch (1) 2 DR mismatch (0)
Panel Reactive Antibody = 80%	4	Same
Pediatric		
Age < 11 years	(4)	Same
Age 11–18 years	(3)	
Donation status (previously a living kidney donor)	(4)	Same

¹UNOS Policy 3.5.11.

²Adopted by UNOS Board of Directors, 11/14/02.

Allocation point changes:

1 Points only for 0–1 DR mismatch combination (see above).

2 ABO type O zero mismatch kidneys should only be offered to B or O (not A) candidate. ABO type B is prevalent in African American recipients and ABO type A candidates have a relatively short waiting time.

3 Expand the priority given to zero mismatched patients with PRA > 30%. A 0-mm kidney may be the best opportunity for a negative cross-match in a patient even less highly sensitized than 80% panel reactivity when multiple HLA matched candidates are identified.

Allocation priority to previous live kidney donors: UNOS Policy 3.5.11.6 currently assigns four points to individuals who have previously donated a vital organ for transplantation and subsequently develop renal insufficiency requiring kidney transplantation (30). Allocated points should be sufficient to ensure that no such candidate would face an extended wait for a suitable kidney from a standard donor.

Time waiting for a transplant should be calculated from the point at which a patient begins maintenance dialysis, not upon completion of transplant evaluation: This proposal is designed to eliminate the advantage of patients with early access to the list and thereby neutralize bureaucratic barriers that may delay access to transplant programs and the completion of the work-up process (31). In addition, it was recommended that patients continue to accrue waiting time while maintained in inactive status on the waiting list.

Work Group 3: Management of the Kidney Transplant Waiting List

The mandate of the Managing the List Work Group was to devise practical ways to cope with the lengthening waiting list in order to facilitate the rapid placement of cadaver kidneys to a prepared population of potential recipients.

The challenge facing the group was to ensure patient readiness while minimizing the repetition of onerous and expensive testing.

Maintaining and monitoring the list

Whereas guidelines have been published and updated representing the consensus opinion of the transplant community regarding the preparation of patients for transplantation (32), there are no accepted guidelines for maintaining and monitoring the health of patients once they are on the list. The health, particularly the cardiovascular health, of the chronically ill patients that are placed on the list may deteriorate in the spent waiting, a potential causative factor in the well-documented relationship between long-term graft survival and years spent on dialysis (33). The problem is compounded by the emphasis on HLA matching in allocation, making it difficult to anticipate when any given patient will be called for a much-awaited transplant. Thus, current allocation policies require all listed patients to be medically ready for transplantation at all times, a nearly impossible charge given the increasing size of the list (see below). The consequences of patients not being ready are either cancellation of a transplant or performance of a transplant under unnecessary or unrecognized risk (4).

Currently, most kidneys are transplanted into unsensitized patients (PRA < 10%) with the longest waiting time. Adoption of the proposal to delete matching at the B locus from allocation should magnify this trend, allowing transplant centers to better predict which listed patients are most likely to receive a kidney offer within a defined period of time. Thus, this work group recommended: *The transplant center should ensure that unsensitized patients in each blood group with the longest waiting time are medically suitable for transplantation.* This strategy could be implemented immediately to bring some measure of medical order to an otherwise unmanageable and relentlessly expanding list of patients (34). It will be a necessary component of allocation for ECD kidneys (see below).

Other remedies to manage the list

Communication: A web-based electronic system (UNet) is currently used for communication between transplant programs and the United Network for Organ Sharing (UNOS). A similar system should be designed for communication between dialysis centers, transplant programs and histocompatibility laboratories. For the present, Managing the List Work Group participants recommend that each transplant program designate a senior nurse coordinator as a 'wait-list manager' with the specific function of communicating with listed patients and their dialysis units. A parallel function should be designated to a staff member of each dialysis center. It is the responsibility of the transplant center to define and promulgate protocols that specify requirements for health monitoring and reevaluation of wait-listed patients. At the very least the transplant program wait list manager and the patient should communicate by telephone or preferably, in person, on an annual basis.

Preventive health measures: Clinical practice guidelines for the care of patients with ESRD so called DOQI (Disease Outcome Quality Initiative) guidelines – have been developed, disseminated, and updated by the National Kidney Foundation (35). These recommendations should be applied consistently to for all wait-listed patients.

Cardiovascular testing: There is widespread agreement among transplant programs that repeated cardiovascular surveillance is required for many patients awaiting a cadaver kidney transplant, with more intense monitoring for 'high-risk' patients (36). There is no firm consensus, however, as to who should be tested, at what interval, and with what modality. The recommendations listed in Table 4 reflect current standards as reported in a recent survey of transplant programs (3). They emphasize evidence that diabetic ESRD patients represent a particularly high-risk group, that dialysis patients are susceptible to progressive cardiomyopathy, coronary artery disease (CAD) and aortic stenosis, and that risk factors applicable to the general population may be relevant to patients with ESRD. Others have supported these recommendations (37).

The Managing the List Work Group proposed that the modality used for routine cardiac surveillance be a stress echocardiogram or a combination of rest echocardiography and nuclear stress imaging. Coronary angiography should be performed if the noninvasive imaging is suggestive of significant coronary artery disease.

While a patient awaits availability of a suitable kidney, all potentially reversible risk factors for CAD should be addressed: hyperlipidemia, hypertension, smoking, obesity and sedentary life style (36). Any change in clinical status (e.g. new cardiac event, worsening congestive heart failure) should be reported to the transplant center and mandates reevaluation.

Screening for infectious diseases: Since new onset of infection or change in exposure or risk alters the approach to transplantation in affected candidates, some monitoring of wait-listed patients may be warranted. Current recommendations (as discussed by this work group) are listed in Table 5.

Screening for anti-MHC reactivity: The current ASHI standards (www.ashi-hla.org) and UNOS bylaws (www.unos.org) do not stipulate specific strategies for anti-HLA antibody screening, but recommend periodic testing of patients to detect sensitization and require individual laboratories to develop clinically appropriate policies regarding the frequency of testing.

Many centers monitor patients for sensitization monthly, a practice, which evolved in the 1970s and 1980s when waiting times were far shorter than today and when dialysis patients were likely to receive frequent blood transfusions to control anemia. Such a practice may now be excessive. Representatives of the immunogenetics community on the Managing the List Work Group suggested that a reasonable approach would be to screen serum from each transplant candidate at the first encounter and for 2 subsequent consecutive months. If a specimen tests positive for Class I or Class II antibodies, specificity analysis should be performed. Antibody screening should be

Table 4: Recommendations for cardiac surveillance of waitlisted patients [from references (3,36)]*

Initial evaluation negative:
Diabetic ESRD — annual
Non-diabetic 'high-risk' — biannual
'low-risk' — every 3 years
Initial evaluation positive:
No prior revascularization — annual
Prior percutaneous coronary intervention — annual
Post coronary artery by-pass -- successful** - every 3 years then annual — incomplete – annual
Asymptomatic moderate or worse aortic stenosis — annual echocardiogram

*High-risk (more than 20% per 10 years cardiovascular event rate risk) according to Framingham data includes those with two or more 'traditional' risk factors, a known history of coronary disease, LV ejection fraction = 40%, or peripheral vascular disease. **Complete revascularization of all target vessels.

Table 5: Recommendations for surveillance of some infectious diseases among wait-listed patients

Human immunodeficiency virus (HIV)	Annual screening only for high-risk individuals
Hepatitis C Virus (HCV)	Annual screening for ELISA (–) patients (38,39) ELISA (–) patients with abnormal transaminase levels may require PCR testing HCV (+) patients require ongoing care; histologically advanced disease may preclude transplantation
Hepatitis B Virus (HBV)	Previously unexposed patients should undergo immunization, with annual testing of antibody levels and appropriate booster doses if indicated
Tuberculosis	PPD positive patients should receive standard chemoprophylaxis and annual chest X-ray (40)
Strongyloides	Annual screening in endemic areas (39)
Epstein Barr virus, toxoplasmosis, cytomegalovirus, herpes simplex	Annual screening not indicated

performed quarterly thereafter to monitor for the development of anti-HLA antibodies in nonsensitized patients and to monitor changes in the specificity of anti-HLA antibodies among sensitized patients.

Histocompatibility laboratories should be encouraged to perform detailed specificity analysis of serum from sensitized patients. While it is not yet statistically or scientifically possible to predict a negative cross-match, appropriate specificity analysis can identify, and eliminate, inappropriate donor/recipient pairs. The immunogenetics community is working towards cross-match prediction algorithms. Algorithms to predict which patients are likely to be offered an HLA-matched kidney through the national program could help ensure that such patients are medically prepared (41).

Removal from the transplant list: Patients who develop irremediable contraindications to transplantation (e.g. metastatic cancer, severe coronary disease) should be removed from the waiting list. An unofficial policy of leaving such patients on the list for ‘compassionate’ reasons should be disallowed. Patients with potentially remediable contraindications to transplantation (e.g. diabetic foot ulcer, localized malignancy) should be put ‘on-hold’ (status 7) at UNOS. The current policy of not permitting on-hold patients to accrue waiting time should be discontinued, since it may represent a disincentive to accurately report a patient’s status. Patients should be put on medical hold only for a predetermined period of time that is determined by the transplant program based on the nature of the contraindication to transplantation. Return to active status by the OPTN should then occur automatically.

Work Group 4: Identifying Appropriate Recipients for Expanded Criteria Donor Kidneys

Graft survival is significantly worse after transplantation of kidneys procured from deceased donors over 55–60 years of age (5,22,42), leading to the designation of marginal or expanded criteria donors. Organs procured from such

donors, as well as from donors with a history of hypertension and/or diabetes mellitus, are commonly discarded after procurement (43,44). Transplant centers frequently turn down these kidneys due to a perceived mismatch in physiology or function between the donor and the recipient, and out of concern for poorer outcomes and increased cost. This sets up a vicious cycle where these kidneys, even if ultimately placed, have gone through many offers over a protracted time interval prior to transplantation.

In a study by Ojo, the survival benefit in recipients of expanded donor kidneys was assessed by comparing their mortality risk to that of wait-listed dialysis patients (22). Despite lower overall graft survival rates than with standard donors, transplantation of expanded donor kidneys still conferred substantially increased longevity compared to maintenance dialysis. Port recently studied United States Renal Data System records to determine donor characteristics associated with increased graft failure (44). There was a 70% or greater risk of graft failure (compared to a reference group of donors aged 18–39) for all kidneys from donors over age 60 as well as those between age 50 and 59 with at least two of the following characteristics: hypertension, serum creatinine above 1.5 mg/dL, and cerebrovascular accident as the cause of death. As a group, these higher risk donors, now termed expanded criteria donors (ECD), had a relative risk of graft failure at least 1.7 times greater than non-ECD kidneys. The ECD group accounted for 14.8% of deceased donor kidneys transplanted in the US between 1995 and 2000. However, 38% of procured ECD kidneys were discarded compared to 9% for all other kidneys. Merion and coworkers found the long-term mortality rate after ECD kidney transplant to be lower than in a reference group of dialysis-dependent wait-list candidates (45). However, the time required for equalization of survival in the transplanted and wait-list groups was longer for recipients of ECD kidneys.

These data, combined with the logistical difficulties in successfully utilizing ECD kidneys, provided the scientific basis for a modified national cadaveric kidney allocation policy. The goals of this modified policy were to facilitate

the expeditious placement, shorten cold ischemia time, increase utilization, and reduce discard rates of ECD kidneys. Following lengthy deliberation in the transplant community and extensive public discourse, the Organ Procurement and Transplantation Network (OPTN) approved the new policy in November, 2001. Patients on the wait-list must now choose whether to be considered for all cadaveric kidneys, including ECD kidneys, or to be offered only those from non-ECD (standard) donors. Patients who agree to accept an ECD kidney should consider: (i) the added risk of graft failure compared to a non-ECD graft; (ii) the possibility of a shorter wait for transplantation; and (iii) the potential for reduced mortality vs. remaining on the wait-list.

The Expanded Donor Work Group addressed the question of identifying appropriate recipients for kidneys from ECD donors. Recommendations were based upon the principle of improving access to organs for patients whose life expectancy is less than their predicted waiting time, recognizing the influence of disparities in organ availability and waiting time among organ procurement organization service areas and OPTN regions (Table 6).

Allocation of ECD kidneys is based almost exclusively on waiting time, a policy that should minimize the inability of HLA-based algorithms to accurately and prospectively identify candidates likely to be nearing transplantation (see above). Thus, ECD kidneys are now offered first to 0-antigen mismatched candidates, with a relatively short time limitation for a decision (2h); and next, for all other eligible patients, locally, then regionally, and then nationally, based upon time waiting and not HLA matching. Efficient management of the waiting list for ECD kidneys requires that transplant centers ensure that the top patients (by waiting time) in each ABO blood type are ready for transplant when an organ is offered.

The Work Group also discussed other logistic and pragmatic issues that might result in delayed allocation of ECD kidneys. The inclusion of large numbers of patients with elevated panel reactive antibody levels would result in a high frequency of positive cross-match, obviating the objective to improve outcomes by reducing cold ischemia time. Thus, highly sensitized patients (PRA = 30%) may not be optimal candidates for ECD kidneys.

Oversight and review of the ECD allocation system should occur at regular intervals. The Expanded Donor Work

Group suggested that the SRTR analyze turndowns and transplant outcomes by donor relative risk, patient characteristics, transplant center, and organ procurement organization (OPO), and report to the OPTN Kidney/Pancreas Committee for review and action as necessary. Finally, it was suggested that the SRTR periodically reevaluate the criteria that are used to define ECD.

The Work Group recognized that there are both incentives and disincentives for the use of ECD kidneys. Procurement and transplantation of ECD kidneys will likely result in improved OPO performance, although there may be additional costs that may be passed on to the transplant centers through kidney acquisition charges. For the transplant center, the costs of performing ECD transplants will likely be higher than non-ECD kidneys, exerting potentially deleterious effects on the financial viability of those that aggressively utilize ECD kidneys. Increased use of ECD kidneys will, almost by definition, result in lower overall graft survival rates for the transplant center and the nation as a whole. Analysis of cost data for ECD and non-ECD transplants should be undertaken to determine whether a modifier to enhance reimbursement for the kidney transplant diagnosis-related group (DRG 302) is justified.

Utilization of ECD kidneys also brings up a variety of issues relating to informed consent. The participants in the Expanded Donor Work Group recommended that that the risks and benefits for the patient should be discussed prior to placing a candidate on the ECD wait-list and that informed consent should be documented in writing at that time. Minimum informational elements for patients contemplating acceptance of an ECD kidney should include:

- 1 The increased likelihood of delayed graft function;
- 2 Decreased graft survival when compared to a non-ECD kidney;
- 3 Increased longevity compared to remaining on dialysis;
- 4 The potential for decreased waiting time; and
- 5 Benefit of transplant prior to potential dialysis-related morbidity and mortality.

Centers that choose not to utilize any ECD kidneys should nevertheless consider discussing the existence of the ECD list with all potential candidates.

Table 6: ESRD patients most likely to receive optimal benefit from ECD kidneys

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- Transplant candidates ≥ 60 years of age
 - Diabetic transplant candidates ≥ 40 years of age
 - Dialysis patients with failing or limited options for vascular access
 - Patients faring poorly on dialysis – by medical or quality of life criteria
 - Unsensitized patients
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N.B. This report was reviewed by the Council of the American Society of Transplant Surgeons and the Council of the American Society of Transplantation in the process of its submission for publication, and independently from the editorial review of the American Journal of Transplantation. An executive report of the meeting was submitted to the Division of Transplantation of HRSA within 30 days of the conclusion of the meeting. Notwithstanding the sponsorship of the meeting by the AST, ASTS, DOT and NKF, the report does not necessarily reflect the policy of these sponsoring organizations.

The leadership of the conference (by work group chairs) was selected following a review of the objectives of the conference by the Council of the ASTS and AST. The designation of each work group chair was a part of that review process. Broad representation was sought among the transplant community. The Work Group chairs were responsible for the selection of each work group participants.

Participants by Work Group

Work Group 1: Access to the List

Chairs: Patricia Adams, MD and Robert S. Gaston, MD

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