

Waiting Time for Transplantation

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Introduction

Ensuring equitable access to solid organ transplantation while maintaining utility is the goal of organ allocation.

Equity can be defined as fairness in access to transplants for all those in need. Equity is difficult to achieve and some patients will always be disadvantaged (i.e., those with uncommon blood types or who are broadly sensitized). In the current era, in which the demand for transplantation far exceeds the supply of transplantable organs, equity is maximized when organs are allocating according to waiting time.

Utility (optimizing the function of the available supply of transplantable organs) has historically been determined by HLA matching in organ allocation schema. Although the degree of HLA matching remains an important determinant of allograft survival (the difference in 10 year graft survival between the least matched and best matched kidneys is approximately 18% with approximately half of this due to the benefit of a zero mismatch and the remainder spread equally over the various grades of HLA matching), [1]HLA matching has been de-emphasized in many organ allocation algorithms in an effort to maintain equity with increased emphasis on waiting time (table 1).[1] Of importance because the majority of deceased organ donors are Caucasian, it is now evident that organ allocation schema emphasizing HLA matching inadvertently disadvantage non-Caucasian patients.

Table 1. UNOS Point System for Cadaver Kidney Allocation Before October 2002 With Subsequently Implemented, Adopted, and Proposed Changes

Category	Points Assigned Before October 2002	Changes
Time of waiting	1 point assigned to the patient waiting the longest, fractions proportionately assigned to the remainder, 1 additional point for each full year waiting	No change
Estimation of wait	From time of UNOS registration after GFR < 20 mL/min	From time of dialysis or GFR <20 mL/min*
Antigen mismatch	Time lost during inactivity 7 points for 0 B and DR mismatch 5 points for 1 B or DR mismatch 2 points for 2 B or DR mismatch	No loss for inactivity† 2 points for 0 DR mismatch 1 point for 1 DR mismatch‡
Panel-reactive antibody	4 points, if panel-reactive antibody > 80%	No change
Pediatric	4 points for age < 11 y; 3 points for age of 11 y but < 18 y	No change
ECD kidneys	No category	Waiting time-based allocation‡

*Proposed changes.

†Adopted.

‡Subsequently implemented.

Given the marked regional differences in access to transplantation across Canada, the optimal weighting of waiting time and HLA matching in regional organ allocation schema may vary. The purpose of this document is to define different statistics used to describe patient access to transplantation, and to discuss the impact of delayed access to transplantation on pre and post transplant outcomes.

1. Definitions

A variety of terms are used to describe the time patients wait for transplantation:

1.1 Median time to transplantation This statistic reports the time at which half of the candidates will have received a transplant, among all of those initially listed.

If more than half of the candidates are removed or die before receiving a transplant, or if the time is longer than the longest follow up time for candidates included in the calculation, then this statistic cannot be reported. In general the median waiting time to transplantation is longer among older registrants on the waiting list because older registrants have a greater chance of dying before they receive a transplant (see figure 1).[2] The median time to transplantation considers all candidates who are initially registered on the waiting list and is generally longer than the median waiting time. The median time to transplantation is most useful for candidates when they are first placed on the waiting list.

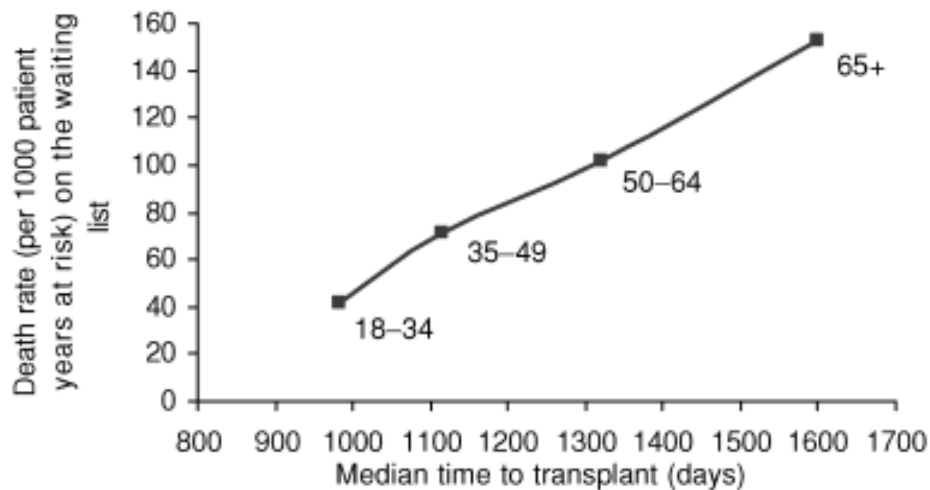


Figure 1 Adapted from reference 2. Median time to transplantation is longer in older patients because older patients have higher death rates.

1.2 Median Waiting Time This statistic reports the time at which half of the candidates registered on the waiting list would receive a transplant, if they remained active on the list. It is calculated using the successive rate of transplantation seen at each time after registration, among candidates who remain active on the waiting list (dropping candidates when they die or are removed from the waiting list and excluding inactive times). This time is generally shorter than the median time to transplantation since it uses transplant rates among those who remain active on the waiting list.

1.3 Waiting time is a term that is somewhat loosely used. In general this term applies to the time that transplant recipients (not candidates) actually waited for transplantation. It may be calculated as the transplant date – the date of first dialysis, or alternatively as the transplant date – the date of registration to the waiting list. The calculation of waiting time may be from the date of first chronic dialysis treatment or from the date of activation to the transplant waiting list. Patients may be activated to the transplant waiting list prior to the initiation of chronic dialysis treatment (preemptive

listing). Preemptive listing is permitted when native kidney function drops below an arbitrary cut-off (for example UNOS permits patients to be wait-listed at a glomerular filtration rate ≤ 20 ml/min).

Waiting time may or may not include the time that patients are inactive on the transplant waiting list because of temporary medical illness. Until June 2003, UNOS only permitted a maximum of 30 days of waiting time while inactive. This policy was subsequently amended so that all inactive time is now credited as waiting time. The start date used to calculate waiting time, and whether time accrued while a patient is inactive on the waiting list is included or excluded from the calculation should be specified in order to interpret the waiting time statistic.

1.4 Limitations of the above statistics

All statistics describing the waiting time of patients provide only limited information about access to transplantation.

Because the above statistics only include patients registered on a transplant waiting list or transplant recipients they provide no information about access to transplantation among all end stage renal disease patients who may benefit from transplantation. It is clear that many such patients never gain access to transplantation (see table 2).[3]

Year Post ESRD	Living Donor Tx	Deceased Donor Tx	Dialysis, no prior tx, wait-listed	Dialysis, no prior tx, not wait-listed	Dialysis, failed tx, wait-listed	Dialysis, failed tx, not wait-listed
1 n=4723	13.6%	8.3%	23.5%	53.9%	0.3%	0.4%
2 n=4192	17.4%	16.5%	22.5%	42.4%	0.6%	0.6%
3 n=3639	20.1%	23.3%	19.1%	34.8%	1.0%	1.7%
5 n=2679	22.7%	35.3%	11.2%	24.4%	2.7%	3.8%

Table 2. Status of dialysis treated end stage renal disease patients aged 30-39 years at different time points after dialysis initiation in the United States on January 1, 2002. Twenty-four percent were never waitlisted or transplanted five years after onset of ESRD (data from reference 3).

2. Waiting times in Canada

Figure 2. shows the waiting time of deceased donor kidney transplant recipients (the time the transplant recipients had waited from the date of first dialysis until transplantation; the medians are shown therefore 50% waited longer than the time shown) as reported by the Canadian Organ Replacement Register (CORR) for the year 2003. There is significant regional variation in median waiting times across Canada.

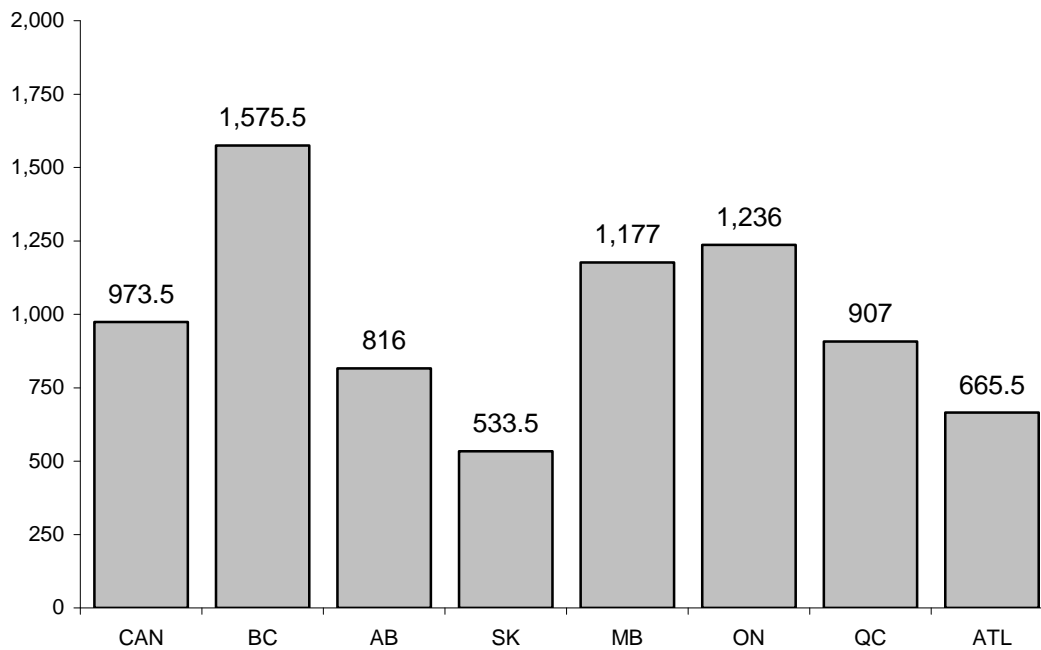


Figure 2. Source Canadian Organ Replacement Register. Time calculated as date of transplantation minus date of first dialysis. Medians are shown.

Figure 3 shows the projected median time to transplantation of incident non-diabetic dialysis patients 18-39 years of age in Canada between 1996 and 2000.[4] National information regarding waitlist status of end stage renal disease patients is not available, thus the projected times do not meet the strict definition of median time to transplantation. However, because most patients in this age group would normally be medically eligible for transplantation - the times shown represent a reasonable approximation of the median time to transplantation for this age group. Once again significant regional variation is noted.

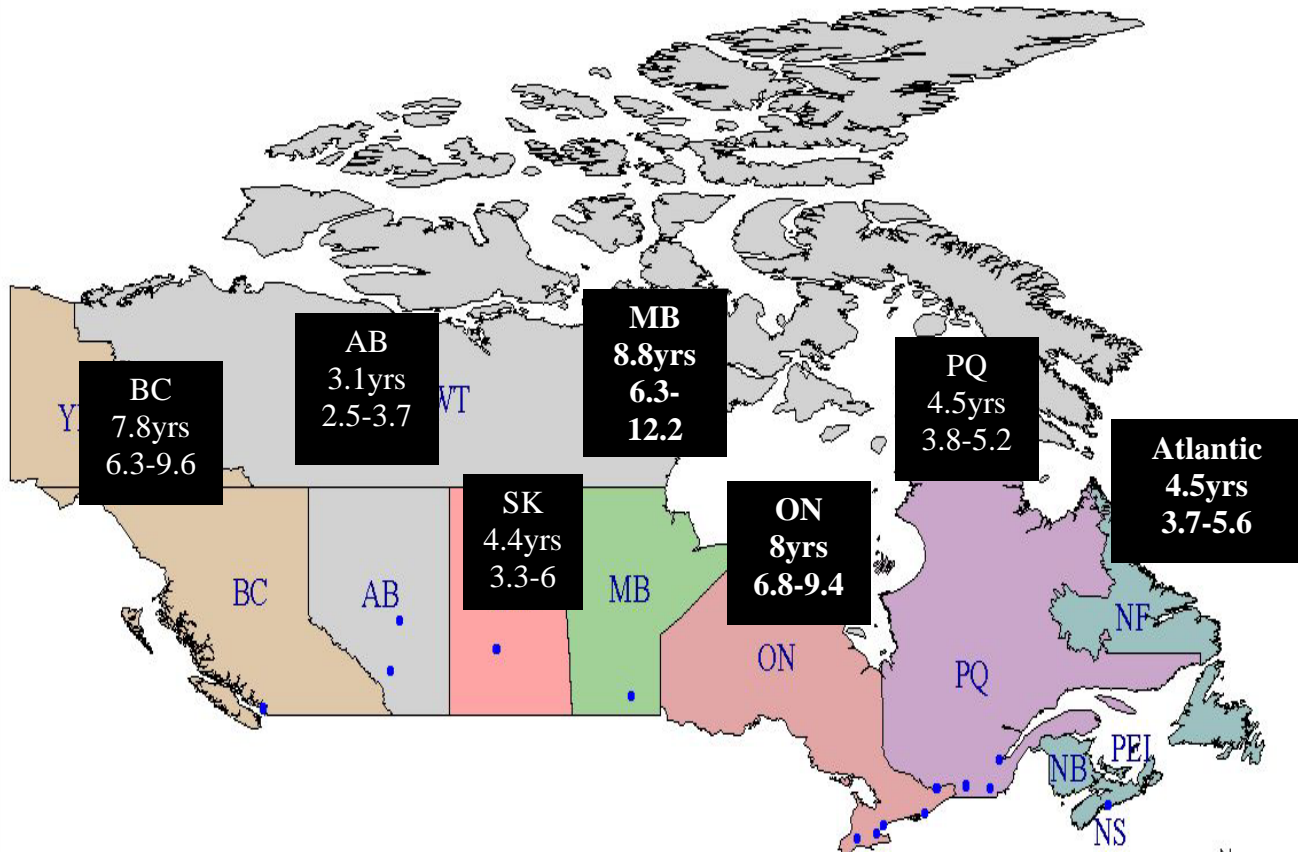


Figure 3. Predicted time to 50% transplantation from a deceased donor (from date of first dialysis). Non-diabetic patients 18-39 years. All of Canada 6.1 years (5.3, 6.9) (data from reference 4).

3. Impact of waiting time on pre and post transplant morbidity and mortality

3.1 Preamble

Because patients can be treated with dialysis for prolonged periods of time, the consequences of delayed kidney transplantation may not be immediately evident and this is different from transplantation of other solid organs where death is more frequently the immediate consequence of delayed transplantation. For example younger patients may not die while waiting for a kidney transplant, but will have a decreased projected life span when transplanted after a lengthy waiting time. Thus kidney transplantation is clearly life saving. Because younger patients have a longer life expectancy than older transplant recipients, the number of life years lost as a result of delayed transplantation is greater in younger patients.

The consequence of delayed transplantation may be considered as immediate (death or development of comorbid conditions on the waiting list), or delayed (decrease in survival benefit of transplantation related to prolonged exposure to dialysis while waiting for a transplant).

3.2 Immediate consequences

The annual death rate among waitlisted patients in the United States is approximately 6% in non-diabetic patients and 10% among diabetic patients.[2] There is limited data regarding morbidity and mortality among wait-listed ESRD patients in Canada. Published data from 604 waitlisted patients in British Columbia between 1998 and 2002 would suggest that death rates are somewhat lower than those in the United States.[5] The annual death rate was 1.6/100 patient years overall (95% CI, 1.2 to 2.2) and the probability of death per year on the waiting list for patients with and without diabetes was 3.4% (95% CI 2.0 to 5.9) and 1.2% (95% CI 0.8 to 1.9) respectively. The cardiovascular event rate (including cardiovascular death, myocardial infarction, PTCA, CABG, completed stroke, and removal from the waiting list for cardiac reasons) was 6.1/100 patient years (95% CI 5.1 to 7.2) and was relatively constant during the first three years of waitlisting (5.3 to 6.6 per 100 patient years, 95% CI 2.7 to 9.3/100 patient years). Possible reasons for the lower event rate in the B.C. compared to UNOS include a greater proportion of Asian patients in B.C. (who are known to have superior dialysis survival than non-Asians), and a higher proportion of patients who were activated to the waiting list before starting dialysis. The age, presence of comorbid conditions, and diabetic status of the B.C. and UNOS waitlisted patient populations were similar.

Differences in dialysis survival have not for the most part influenced organ allocation schema. White patients, diabetic patients, and patients with known cardiovascular disease (CVD) tolerate dialysis poorly and have decreased dialysis survival compared to non-white, non-diabetic and CVD free patients.[6] Although patients who run out of dialysis access are prioritized for transplantation in many organ allocation schema, and children are prioritized because of poor growth and development on dialysis, other examples in which patients are prioritized for transplantation because of negative health consequences on dialysis are relatively rare. A proposal to prioritize diabetic patients for transplantation in the United States was not enacted because of the potential disadvantage to non-diabetic patients.[7]

3.3 Delayed consequences – Net benefit calculations

The longer patients wait on dialysis before transplantation, the worse their post-transplant outcomes.[8, 9] Patients who wait for a transplant for prolonged periods of time may develop comorbid conditions, that were not present at the time of initial activation to the waiting list, but which could have a major impact on their post-transplant course. The best outcomes are achieved when dialysis is avoided entirely (preemptive transplantation).[10] The unfavorable relationship between time spent on dialysis and outcome is progressive up to four years, which confers a about a 70% additional risk of mortality and graft loss compared with preemptive transplantation.[8]

In order to quantify the impact of delayed transplantation, *net survival benefit* (life expectancy with transplantation – life expectancy without transplantation) has been determined for patients in the United States with waiting times of up to three years.[11] The main findings of this study were that although increased waiting time is associated with a decrease in the net survival benefit from transplantation, the decrease in the anticipated survival benefit of transplantation when patients waited up to three years was relatively modest and all patients still derived a survival advantage from transplantation (Table 3). An important additional finding of this study was that the *relative* survival benefit of transplantation was in fact greater in patients who had prolonged waiting times prior to transplantation. The reason for this somewhat paradoxical finding was explained by the fact that the mortality rate of wait-listed patients progressively increased as a function of waiting time while the

mortality rate of transplanted individuals did not show the same progressive increase with waiting time (Figure 4).

	Without transplant Expected life years	Transplant at any time during follow-up^c		Transplant after minimum waiting time of 1 year		Transplant after minimum waiting time of 2 years		Transplant after minimum waiting time of 3 years	
		Expected life years	Benefit	Expected life years	Benefit	Expected life years	Benefit	Expected life years	Benefit
All patients	7.9 (7.5,8.2)	17.7 (16.7,18.7)	9.8	15.0 (14.2,15.8)	7.1	13.9 (13.1,14.6)	6	13.5 (12.7,14.2)	5.6
Age									
0–19	12.0 (9.2,14.7)	29.2 (23.8,34.6)	17.2	20.7 (16.6,24.9)	8.7	19.0 (15.0,23.0)	7	18.1 (14.3,21.9)	6.1
20–39	9.5 (8.8,10.1)	24.3 (22.4,26.1)	14.8	19.5 (18.0,21.0)	10	17.5 (16.2,18.9)	8	16.9 (15.6,18.2)	7.4
40–59	7.6 (7.3,8.0)	17.0 (16.0,18.0)	9.4	14.7 (13.8,15.5)	7.1	13.6 (12.8,14.4)	6	13.2 (12.4,14.0)	5.6
60–64	6.5 (6.1,6.9)	12.7 (11.7,13.7)	6.2	11.4 (10.5,12.3)	4.9	10.8 (9.9,11.6)	4.3	10.6 (9.8,11.4)	4.1
65–69	5.8 (5.4,6.2)	11.1 (10.1,12.1)	5.3	10.1 (9.2,11.0)	4.3	9.6 (8.8,10.5)	3.8	9.5 (8.7,10.4)	3.7
≥ 70	4.5 (4.0,4.9)	8.2 (7.1,9.2)	3.7	7.5 (6.5,8.5)	3	7.1 (6.2,8.0)	2.6	7.0 (6.1,7.9)	2.5
Male	7.9 (7.5,8.3)	18.2 (17.2,19.3)	10.3	15.4 (14.5,16.3)	7.5	14.2 (13.3,15.0)	6.3	13.8 (13.0,14.6)	5.9
Female	7.8 (7.4,8.1)	16.9 (15.9,18.0)	9.1	14.5 (13.6,15.4)	6.7	13.4 (12.6,14.3)	5.6	13.0 (12.2,13.8)	5.2
Race									
White	7.1 (6.7,7.4)	16.3 (15.4,17.2)	9.2	13.6 (12.8,14.4)	6.5	12.5 (11.8,13.2)	5.4	12.1 (11.4,12.8)	5
Black	9.1 (8.6,9.6)	19.5 (18.2,20.8)	10.4	17.0 (15.9,18.1)	7.9	16.0 (14.9,17.0)	6.9	15.5 (14.5,16.6)	6.5
Asian	10.4 (9.3,11.5)	24.1 (21.1,27.1)	13.7	20.8 (18.2,23.3)	10.4	19.2 (16.8,21.5)	8.8	18.4 (16.2,20.7)	8
Native American	9.7 (8.3,11.2)	21.4 (17.4,25.4)	11.7	19.0 (15.4,22.5)	9.3	17.6 (14.4,20.8)	7.9	17.2 (14.0,20.4)	7.5

	Without transplant Expected life years	Transplant at any time during follow-up ^e		Transplant after minimum waiting time of 1 year		Transplant after minimum waiting time of 2 years		Transplant after minimum waiting time of 3 years	
		Expected life years	Benefit	Expected life years	Benefit	Expected life years	Benefit	Expected life years	Benefit
Cause Of ESRD^f									
Diabetes	5.4 (5.2,5.7)	11.4 (10.7,12.0)	6	9.6 (9.1,10.2)	4.2	9.1 (8.6,9.6)	3.7	8.8 (8.3,9.3)	2.4
Glomerulo- nephritis	10.3 (9.6,11.0)	24.4 (22.6,26.3)	14.1	20.8 (19.2,22.4)	10.5	19.0 (17.5,20.5)	8.7	18.4 (17.0,19.8)	8.1
Other	9.3 (8.7,9.8)	21.6 (20.2,23.1)	12.3	18.3 (17.1,19.5)	9	16.8 (15.6,17.9)	7.5	16.2 (15.1,17.3)	6.9
Ischemic heart disease	7.0 (6.5,7.4)	14.9 (13.7,16.2)	7.9	12.8 (11.7,13.9)	5.8	12.0 (11.0,13.0)	5	11.6 (10.6,12.6)	4.6
Peripheral vascular disease	6.7 (6.2,7.2)	14.6 (13.2,16.1)	7.9	12.2 (11.0,13.4)	5.5	11.4 (10.3,12.5)	4.7	11.1 (10.0,12.2)	4.4
Congestive heart failure	6.8 (6.4,7.2)	13.5 (12.5,14.5)	6.7	11.8 (10.9,12.7)	5	11.0 (10.1,11.8)	4.2	10.7 (9.9,11.5)	3.9
Cerebrovascular accident	6.4 (5.8,7.0)	13.4 (11.8,15.1)	7	11.4 (10.0,12.8)	5	10.6 (9.3,11.9)	4.2	10.4 (9.1,11.6)	4

¹ Projected from the time of activation to the transplant waiting list. Projections based on a time dependent parametric multivariate survival model. Point estimate and 95% confidence interval in years are shown

² Assuming a log-normal distribution for graft failure times

³ Assuming a Weibull distribution for graft failure times

⁴ The difference in expected life years with and without transplantation

⁵ Includes N = 10,985 (56% of all transplant recipients during follow-up) who received transplants with waiting times of ≤ 1 year

⁶ End stage renal disease

Table 3. Expected Life Years¹ with ² and without ³ Transplantation and Benefit ⁴ of Transplantation

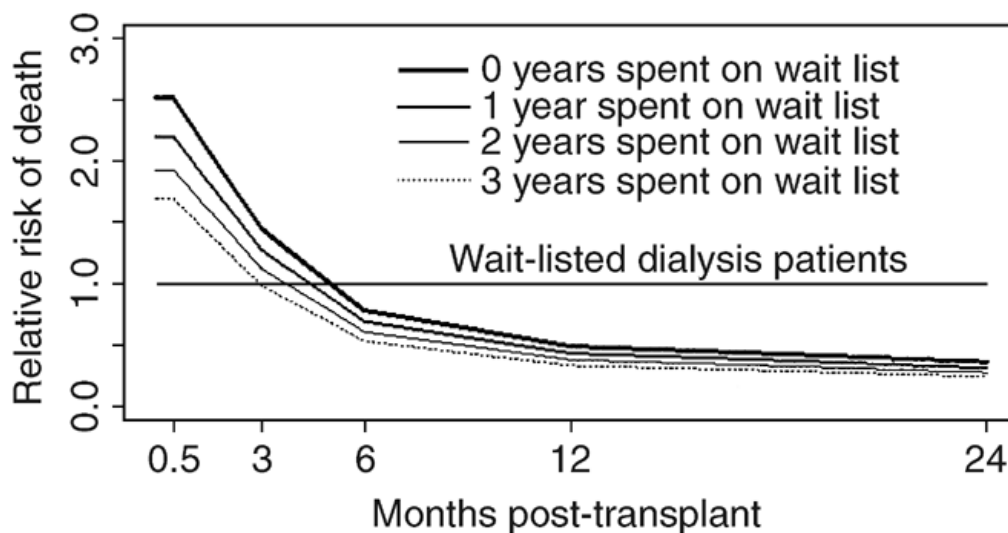


Figure 4. The relative risk of death at different times after transplantation in transplant recipients with progressively longer waiting times compared to subjects who waited the same duration of time but remained on dialysis is shown. Values were adjusted for recipient age, gender, race, cause of end stage kidney disease, comorbid conditions defined at the time of dialysis initiation (ischemic heart disease, congestive heart failure, stroke, peripheral vascular disease), duration of dialysis exposure prior to transplantation and year of placement on the transplant waiting list.

In addition to the duration of waiting time, the magnitude of the anticipated survival benefit of transplantation is determined by clinical factors of the patient population (e.g., age and comorbid conditions, sensitization), and the quality of the donor organ transplanted (e.g., living donor, standard criteria deceased donor, expanded criteria deceased donor).[12] The variable consequences of prolonged waiting time on the survival benefit of transplantation in different patient sub-groups are quantified in Table 3. The largest decrement in the anticipated survival advantage of transplantation with increased waiting time occurred in younger patients and non-diabetic patients. The variation in post-transplant outcome associated with waiting time has not directly been incorporated into most organ allocation schema. In fact incorporating net benefit as factor in determining organ allocation was specifically discouraged in a National Conference on the wait-list in the United States.[7] In contrast, in the United Kingdom, organ allocation favors younger patients who will derive the greatest survival benefit from transplantation.

It is difficult to determine the consequence of even longer waiting times on the survival benefit of transplantation because there is increased selection of only the healthiest patients for transplantation as waiting times progress.[13] Thus the assumption that all waitlisted patients are equally eligible for transplantation becomes more uncertain as waiting times increase. For this reason, it becomes difficult to estimate differences in survival of patients who receive transplants after prolonged waiting compared to those who remain waiting. The fact that there may be a selection bias for transplantation of the healthiest waitlisted patients has significant implications for the validity of net survival benefit calculations (see figure 5).[13]

The transplant community should be aware that inequities in patient selection for transplantation exist even among waitlisted patients, and thus in the absence of randomization of patients to treatment with transplantation versus continued dialysis treatment, net-benefit calculations based on observational data may be biased.

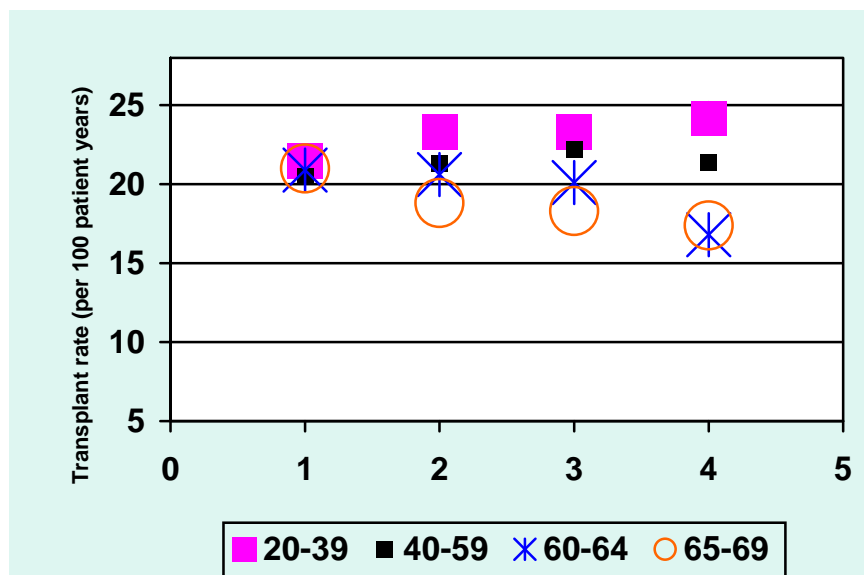


Figure 5. Transplant rate per 100 patient years among wait-listed patients in the United States between 1995-2000. Transplant rates at different time points after activation to the waiting list are shown. Rates are adjusted for gender, comorbidity, blood group and PRA. Transplant rates decrease among older wait-listed patients over time, indicating presence of selection bias for transplantation among wait-listed patients.

A final important consideration regarding the calculation of net-benefit is that these calculations are usually derived from projections based on limited patient follow up. Because mortality rates may change, assumptions regarding the hazard, or instantaneous death rate, based on limited follow up data may be inaccurate. As a result the duration of follow-up as well as the assumptions made regarding patient death rate beyond the actual period of follow-up available should be considered when interpreting net benefit calculations. Recent publications have highlighted the limitations of survival projections in the transplant literature. [14]

4. Pros and Cons of preemptive listing for transplantation

As described above, the best transplant outcomes are achieved when dialysis is avoided with preemptive transplantation.[10] In order to encourage preemptive transplantation, UNOS permits patients to be wait-listed at a GFR of 20 ml/min. The potential disadvantages of this policy are that it further disadvantages patients who may have presented late in their course of native kidney disease due to a variety of socioeconomic and or geographic factors, or due to rapid progression to ESRD. This policy also may inadvertently disadvantage patients who require a lengthy transplant evaluation because of the need for additional specialized investigations or interventions that are either not readily available or best delayed until after dialysis is initiated (i.e., coronary angiography). Additional considerations include the fact that it may be difficult to precisely estimate GFR in patients with advanced kidney function impairment, the fact that renal function may vary dramatically in patients with advanced kidney disease, and that some patients may develop significant symptoms at a GFR > 20 ml/min. As a result of these considerations, standardization of the start of waiting time (i.e., date of first chronic dialysis therapy) may be preferable and has been proposed in the United States.

Standardization of transplantation from the date of dialysis initiation may also facilitate the completion of more thorough assessment of patient suitability prior to activation to the waiting list.

There are some potential draw-backs to standardizing the onset of waiting time to the dialysis start date.[15] Waiting time would be determined independently of the behavior of the patient, and there may be a disincentive for some to initiate and complete the evaluation process expeditiously. To prevent this possibility patients would need to be informed that they could not be allocated a kidney until their work-up had been completed and they were placed on the list, and that delays in listing might lead to them missing an opportunity to receive a kidney. Children, in a critical growth phase, could be potentially disadvantaged by not permitting pre-dialysis accrual of waiting time, and it may be wise to continue to allow children to be waitlisted preemptively.

5. Waiting time based algorithms should facilitate medical surveillance of wait-listed patients

The inclusion of HLA matching into any organ allocation algorithm makes it necessary to ensure that all wait-listed patients are fit for transplantation at all times. Monitoring the medical fitness of a large number of waitlisted patients is a difficult resource intensive task that poses significant challenges for transplant programs. Approximately five percent of deceased donor transplant recipients will die in the first post transplant year.[16] Some of these deaths may be avoided with a predictable allocation scheme that facilitates evaluation of a patient's medical fitness for transplantation close to the time of transplantation. Optimizing the medical surveillance of wait-listed patients will become increasingly important as the number of waitlisted patients continues to increase and with to the aging of the waitlisted population. Of note expanded criteria donor kidneys (ECD) are allocated primarily based on waiting time in the United States, a schema which may be beneficial because older, sicker patients are most likely to be wait-listed for these organs. Indeed a predictable allocation scheme may be an important consideration in decreasing the high early mortality rate seen in ECD recipients.[12]

6. Increased emphasis on waiting time rather than HLA matching and post transplant outcomes

Increased emphasis on waiting time rather than HLA matching in allocation algorithms may have a negative affect on post transplant outcomes. In the United States, the approximate mean number of HLA mismatches for transplanted deceased donor kidneys in is 3.7 (out of a maximum of 6). The number of HLA mismatches expected at random is estimated to be 4.5. Therefore the difference between random allocation and allocation according to the current algorithm in the United States is approximately 0.8 of a mismatch grade. This difference translates into improved graft survival at 10 years of < 2%. The difference in graft half life between a 1 and 6 mismatch transplant at 10 years is approximately 12%.[Danovitch, 2003 #1517] Thus the mean benefit of a 0.8 reduction in mismatch is measured in months. Hence although the benefit of local sharing based on the use of HLA matching according to the current U.S. algorithm are measurable, they are small.

7. Potential disadvantages to emphasizing waiting time in organ allocation

Waiting time based algorithms may lead to decreased referral of patients by primary care providers. Referring physicians may believe that elderly patients or patients with comorbid disease may not survive the waiting time for transplantation or derive little benefit from transplantation after prolonged delay. This may lead to miss opportunities for patient and family counseling regarding the safety and benefits of living donor transplantation, opportunities to participate in living donor exchange programs, or safety concerns regarding the purchase of organs in the developing world. In addition patients who are de facto back-dated to their dialysis start date and thus “activated” to the transplant waiting list without a formal transplant assessment may feel disconnected from the transplant process and may be less motivated to maintain their cardiovascular fitness during the prolonged period of wait listing.

8. Waiting time in failed transplant recipients

It is UNOS policy that patients who return to dialysis with transplant failure within 90 days of transplantation retain their initial transplant activation date and all accrued waiting time. Whether living donor transplant recipients who suffer early allograft failure should be prioritized for deceased donor transplantation has not been addressed in organ allocation schema.

9. Summary

The inclusion of waiting time in allocation algorithms has always been viewed as being fair and equitable. Increased emphasis on waiting time does have the potential to decrease the utility of transplantation and the optimum balance between waiting time and HLA matching and other determinants of utility may differ by region. Algorithms emphasizing waiting time may also facilitate the medical management of transplant candidates and may be favored in regions with a high number of ECD donors.

10. Challenge Questions

10.1 Should waiting time be considered as the main determinant of organ allocation in regions with the following waiting times?

- a) 2 years
- b) 3 years
- c) 4 years
- d) 5 years
- e) 6 years or greater

10.2 Should waiting time be calculated from the date of activation or the date of dialysis initiation?

10.3 If you believe waiting time should be calculated from the date of dialysis initiation, should this preclude preemptive listing?

10.4 How should waiting time be determined for failed transplant recipients? Please consider preemptive waitlisting, patients with early transplant failure.

10.5 Should net benefit be considered in organ allocation schema?

- a) No for all patients
- b) Yes for all patients
- b) No with the exception of children
- c) No with the exception of children and diabetic patients

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