Cost-effectiveness of extending Medicare coverage of immunosuppressive medications to the life of a kidney transplant

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Abstract

Introduction:

Unless they maintain Medicare status through disability or age, kidney transplant recipients lose their Medicare coverage of immunosuppression three years after transplantation. A significant transplant survival advantage has previously been demonstrated by the extension of Medicare immunosuppressive medication coverage from one year to three years between 1993 and 1995.

Methods:

The United States Renal Data System (USRDS) was analyzed for recipients of kidney transplants from 1995-1999. Using a Markov model, we estimated survival and costs of the current system of three-year coverage compared to lifetime immunosuppression coverage. Results were calculated from the perspectives of society and Medicare.

Results:

Extension of immunosuppression coverage produced an expected improvement from 38.6% to 47.6% in graft survival and from 55.4% to 61.8% in patient survival.

The annualized expected savings to society from lifetime coverage was $136 million assuming current rates of transplantation. Medicare would break-even compared to current coverage if the fraction of patients who would use extended coverage was < 32%. The extension would be cost-effective to Medicare if this fraction was < 91%.

Conclusions:

Extended Medicare immunosuppression coverage to the life of a kidney transplant should result in better transplant and economic outcomes, and should be considered by policy makers.

Introduction

The preferred treatment for end-stage renal disease (ESRD) remains kidney transplantation, which is associated with a long-term mortality improvement over dialysis [1]. Transplantation is also less expensive than dialysis [2]. However, as of January 2003, 53,700 patients were waiting for kidney transplantation, with only 14,772 kidneys transplanted in 2002.[3] Preserving functioning kidney transplants is a national priority. Noncompliance is an important barrier to continued transplant function, causing 13%-35% of kidney transplant loss [4-7]. Noncompliant patients lose their transplants or die at rates four times greater than compliant patients.[6]

As the most common payer for ESRD services, Medicare has provided coverage for immunosuppression after transplantation since 1986. Initially, Medicare provided 80% of the cost of immunosuppressives for one year post-transplant. Coverage was gradually extended to three years between 1993 and 1995. In December 2000, the Beneficiary Improvement and Protection Act (BIPA) extended immunosuppressive coverage to life for patients who qualified for Medicare coverage because of age or disability. However, gaps in coverage exist for numerous patients. Many remain at risk of immunosuppression noncompliance due to the cost of medications. Existing policy creates incentives for kidney transplant recipients under the age of 65 to maintain disability status regardless of their physical condition or ability to work.

The $5,000-$13,000 annual cost of immunosuppressive medication [8] contributes to noncompliance. Woodward et al. showed an improvement in graft survival among lower-income transplant recipients after Medicare extended medication coverage from one

to three years post-transplant.[9] Patients residing within lowest income three-fourths of zip codes, with median incomes less than $36,033, were defined as lower-income. With one-year of Medicare coverage for immunosuppression, three-year transplant loss was 4.5% greater in lower-income patients compared to higher-income patients. This difference was statistically significant and disappeared when Medicare changed policy to three-years of immunosuppressive coverage. Woodward and associates determined that Medicare's immunosuppression coverage extension correlated with a 27% relative improvement in graft survival among lower-income patients [9]. Based on the results of this study, we sought to estimate the expected economic and clinical effects of extending Medicare immunosuppressive coverage availability from three-years to the life of the transplanted kidney.

Methods

Data were obtained from the United States Renal Data System (USRDS) [10]. The USRDS collects, analyzes, and distributes data regarding the prevalence, treatment modality, survival, and costs of care of ESRD in the United States. The USRDS links clinical characteristics from the United Network for Organ Sharing (UNOS) kidney transplant registry to Medicare billing and payment records.

Costs:

Costs were calculated from the perspective of society and Medicare, using actual Medicare payments for all medical services provided to patients who used Medicare as the primary payer for their transplant following methods developed by the USRDS [10]. Patients were excluded from economic analysis if no Medicare transplant hospitalization payment was listed, or if the Medicare payment for transplant hospitalization indicated that Medicare was the secondary payer (<$15,000). The annual cost of maintenance dialysis was the USRDS estimate of $67,506 [8]. Medicare payments for organ acquisition are unavailable, therefore, the Centers for Medicare & Medicaid Services estimate of $25,300 per kidney was used [2].

Immunosuppression regimens are highly individualized and are generally higher in the period immediately following transplant than in later years. Immunosuppression payments by Medicare are uniquely distinguishable in the USRDS database for patients who have their immunosuppression prescriptions filled at a non-hospital non-institutional pharmacy. Data is available for Medicare immunosuppression payments through at least 2.5 years post-transplant for patients transplanted between 1995 and 1997. Many patients

during this time period began treatment with azathioprine as part of their immunosuppression. Today, the large majority of patients begin treatment with mycophenolate mofetil, a relatively expensive substitute for azathioprine, and a calcineurin inhibitor, cyclosporine or tacrolimus. Therefore, the average maintenance cost of immunosuppression was estimated as the observed average annualized Medicare payment for immunosuppression at 2.5 years post-transplant for patients transplant in 1995 – 1997 who began treatment with mycophenolate mofetil and a calcineurin inhibitor.

Outcomes

We compared the expected outcomes of extending immunosuppression coverage through the life of the transplant to outcomes of Medicare beneficiaries who currently lose coverage three years post-transplant. The estimates of Woodward et al. [9] were applied to predict the improved graft survival expected from extended coverage. Specifically, we assumed lifetime Medicare immunosuppression coverage would produce a 27% relative reduction in transplant loss in patients without alternative immunosuppression coverage. Outcomes were based on patients who received kidney transplants between 1995 and 1999. Figure 1 illustrates a simplified Markov model of the calculations that were made.

We estimated quality of life with health state values reported in Hornberger's study of 878 first-transplant recipients in the USRDS Case-Mix severity Study. [11] That study assigned health state values for ideal health, successful transplant, dialysis, and death as 1.00, 0.84, 0.68, and 0.0, respectively. Quality Adjusted Life Years (QALYs) were calculated by multiplying health state values by the duration of the health state.

Immunosuppression cost after three-years post-transplant were varied to find levels that would not increase the Medicare budget (break-even) and cost-effective coverage levels. Cost-effective coverage levels were identified that would allow increases in the Medicare budget, balancing the extra expenses with gains in QALYs. The dollar value of one QALY was set equal to the average Medicare payment for one QALY for a patient on dialysis. Calculations were performed through 20 years post-transplant and all costs and QALYs were discounted present value at 5% per year [12]. Costs are reported in U.S. year 2000 dollars, adjusted for inflation using the medical component of the consumer price index [13].

Statistics

Patient and transplant survival was calculated using multivariate Cox regression. Medicare costs were calculated using linear regression analysis. All outcomes were adjusted to mean patient characteristics for recipient age, race, gender, degree of immunologic sensitization as assessed by panel reactive antibody, insulin dependence, donor age and gender, cause of ESRD, duration of pre-transplant dialysis, number of human leukocyte antigen (HLA) mismatches, and year of transplant.

Wait-listed patient survival while on dialysis was calculated following Wolf et al [1], adjusted to mean patient characteristics for age, race, gender, cause of ESRD, and blood type.

Sensitivity Analysis

Sensitivity of the results to variation in input values was assessed by several methods. First, the effect on the results was assessed by varying the input values to the 5th and 95th percentiles of their expected distributions based on standard errors estimated from

the data. Second, a 10,000-iteration Monte Carlo simulation was run with input values drawn from their expected distributions based on their estimated standard errors. Third, utility values and discount rates, which were literature-derived, were varied along plausible ranges.

Results:

Clinical and Financial Outcomes of Study Subjects

The outcomes used for calculations adjusted to average patient characteristics are presented in Table 1. Sample sizes used for estimation were 48,491 for transplant survival, 4,927 for death following transplant failure, 24,333 for waitlist survival, and 26,880 for cost. Modern kidney transplant survival is excellent, with 90.5% one-year and 76.0% five-year transplant survival. The long-term rate of transplant failure, estimated between three-years and five-years post-transplant, was 4.4% annually. The annual death rate following transplantation regardless of transplant survival was 2.9%, which is less than half the long-term death rate while awaiting transplant on dialysis, 6.7%. Further, maintaining transplant function is tremendously important for patient survival with 16.6% of patients dying within one-year following transplant failure and 6.1% more dying the following year. The first year cost of transplantation is impressive at an average $87,400, as is the cost of transplant failure at $137,930 during the year following failure. However, maintenance costs of functioning transplants, at $13,749 annually, are remarkably lower than these early costs as well as the USRDS estimate of the annual maintenance cost of a patient on dialysis at $67,506 [10].

Outcome Benefits Expected From Lifetime Immunosuppression Coverage

Lifetime immunosuppression coverage would reduce transplant failure beginning in the fourth year post-transplant from 4.4% to 3.2% annually. Therefore, expected graft survival improved from 76.0% to 77.9% five years post-transplant and from 38.6% to 47.6% at 20 years post-transplant (Figure 2). Approximately one patient in 9 receiving

extended lifetime immunosuppressive coverage would have a functioning transplant 20 years post-transplant that would have failed earlier under existing coverage.

Median projected patient survival following transplantation was longer with lifetime immunosuppression coverage (27.8 years) than existing coverage (24.4 years), both superior to survival on lifetime dialysis (10.1 years). Approximately one patient in 13 receiving extended coverage would be alive 20 years post-transplant who would have died earlier under existing coverage. In addition, an average 8.8 discounted QALYs per patient are expected with extended coverage, 8.5 discounted QALYs with existing coverage, and 5.4 discounted QALYs with lifetime dialysis.

Cost

Expected discounted costs through 20 years post-transplant were $320,676 with existing immunosuppression coverage, $311,473 with lifetime coverage, and $530,746 with lifetime dialysis. Expected discounted societal savings from lifetime coverage were $136 million annually, given current kidney transplant rates. Therefore, from the societal perspective, it is expected that Medicare immunosuppression coverage for the life of the transplant is a dominant treatment strategy: less expensive and with superior outcomes compared to current policy.

However, Medicare has limited financial responsibility for kidney transplant recipients under current coverage. In cases where extended coverage would be used by a patient, expected discounted Medicare costs, through 20 years post-transplant, were $234,894 with kidney transplant and existing coverage and $268,946 with transplant and extended coverage. Using the costs and outcomes of dialysis as the boundary criteria for

cost-effectiveness analysis, the incremental benefit of a lifetime coverage extension is as cost-effective to Medicare as the overall benefit of dialysis if the average annual cost of immunosuppression to Medicare is no more than $6,784 per patient. Medicare would break-even financially with lifetime coverage if the average annual cost of immunosuppression to Medicare were $2,421 per patient. However, there were 3,007 patients transplanted between 1995 and 1997 and treated with mycophenolate mofetil and a calcineurin inhibitor who had recorded Medicare payments for immunosuppressive medications at 2.5 years post-transplant. Average annualized Medicare payments for immunosuppression in these patients was $7,452. Using this figure, an immunosuppression coverage extension would be cost-effective to Medicare if no more than 91% of patients not already covered used this coverage. Medicare costs would break-even if 32% of patients not already covered used extended coverage.

Sensitivity Analysis:

The societal result that lifetime immunosuppression coverage is cost saving with superior outcomes originates in the survival benefit from coverage extension. However, the results from the perspective of Medicare were sensitive to several parameters, including the graft survival benefit of extended immunosuppression coverage, the discount rate, and dialysis costs. First, the survival benefit of lifetime immunosuppression coverage was varied by 20%. With this, Medicare's budget is expected to break even with 31% - 43% of patients using extended coverage. With this variation, the cost-effectiveness threshold ranged from 75% - 100% of patients. Second, the Transplant Outcomes Research Group recommended 5% as the preferred discount rate for transplant economic

and outcomes studies [13]. However, a 3% discount rate has been recommended by an NIH panel [14]. With a 3% discount rate, Medicare's break-even patient fraction rose from 32% to 38% and the cost-effective faction rose from 91% to 96%. Third, varying the $67,506 estimated cost of maintenance dialysis by 20% generated ranges for the break-even and cost-effective fractions of patients who could use extended immunosuppression coverage of 33% - 41% and 76% - 100% respectively. In any case, considerable room for cost-effective, possibly cost saving, extension of immunosuppression coverage exists from the perspective of Medicare, and we expect society to benefit from lifetime immunosuppression coverage under plausible circumstances.

Discussion:

The consequences of kidney transplant failure are tragic. Within two-years following return to dialysis, 22.7% of patients die. Survivors on dialysis face a strikingly increased risk of death, reduced quality of life, and limited opportunities for return to transplantation. Further, the medical care of dialysis patients is remarkably more expensive than for patients with functioning transplants. Several studies have linked immunosuppression noncompliance to increased transplant failure risk in kidney transplantation [15-19]. Immunosuppressive medications are expensive, with up to 50% of noncompliance attributed to high costs of therapy [19-22]. This suggests a great risk of graft failure and death in kidney transplant patients without immunosuppression drug coverage due to cost-driven noncompliance [9].

We have shown the clinical and economic costs of transplant failure, demonstrating a financial incentive, in addition to a humanitarian one, to prevent transplant failure. Interestingly, the results are not specific to patients who received Medicare-covered transplants because Medicare assumes full coverage of any uninsured kidney transplant patient upon return to dialysis. Therefore, in addition to the benefit to society of coverage for such patients, it may be cost-effective or cost-saving to Medicare to offer lifetime coverage to uninsured kidney transplant patients regardless of Medicare eligibility.

Not all eligible patients would find it in their interest to use Medicare for immunosuppression coverage. Many have private pharmacy benefits available that are superior to Medicare's 20% required co-payment. Therefore, a policy of Medicare as secondary payer could direct patients to private pharmacy benefits when available, greatly

reducing the fraction of patients covered by Medicare. This would target patients at risk, those with no alternative immunosuppression coverage, while generating the benefits of universal lifetime immunosuppression coverage.

Patients with Medicare coverage because of disability who are not truly disabled fear returning to work will trigger a reevaluation of their disability status. Therefore, we expect lifetime coverage will increase work incentives for kidney transplant patients because patients will no longer need to maintain disability status to receive immunosuppression coverage. This may yield more privately insured patients and increase Medicare, and other, tax revenue. As of December 1995, 38% of functioning kidney transplant recipients were receiving Medicare due to disability. The number of patients on disability solely to maintain Medicare coverage is unknown [8]. However, it has been reported that as many as 67% of unemployed transplant recipients remain unemployed to maintain insurance coverage [23-25].

Our estimates were subject to a number of limitations. First, Woodward's estimate of graft survival benefits of extended coverage may be conservative [9]. Classifying income by zip code is an imperfect estimate of individual incomes. It is almost certain that some proportion of both lower-income and higher-income patients in Woodward's study were without private insurance benefits after Medicare coverage ended. Policy targeting patients without private insurance benefits may provide a greater benefit than this estimate.

Our results also assume that inability to afford immunosuppression leads to noncompliance and transplant failure. Reasons for noncompliance are multifactorial, with the majority of reported cases being of unknown etiology [4]. However, a compelling argument for lifelong immunosuppression still exists given observed changes in transplant

survival with past changes in immunosuppression coverage, as neither the current nor the previous analysis relied directly on noncompliance rates [9].

Further limitations of this study include reliance on estimates of the future based on current observation. In an ideal setting, future outcomes of new policy would be known prior to implementation. In reality, it is unlikely that a randomized prospective study of lifetime immunosuppression coverage is possible. Therefore, we expect that this policy decision will have to be made using existing information, such as that presented here. However, we do feel it would be wise to prospectively follow changes in outcomes following a change in policy to lifetime immunosuppression coverage.

We have defined a cost-saving opportunity for society to improve outcomes of kidney transplant recipients burdened by the cost of necessary immunosuppressive medications. Since 1978, our society decided to support kidney transplantation, a decision that has improved the length and quality of life for thousands of Americans with ESRD. However, financial support of kidney transplantation has been incomplete, leading to transplant failures in the years after Medicare coverage ends. Current policy creates a disincentive for transplant recipients to return to the workforce, and it risks unnecessary transplant failure and death in those unable to afford therapy. It is time to make lifetime immunosuppression coverage available to all kidney transplant patients without alternatives.

Table 1. Adjusted Average Outcomes and Costs of Study Subjects

Transplant Survival	
Sample Size	***48,491***
Transplant survival at year 1	***90.5%***
Transplant survival at year 2	***86.9%***
Transplant survival at year 3	***83.2%***
Transplant survival at year 5	***76.0%***
Long term transplant loss rate (Calculated from year 3 through year 5)	***4.4%***
Proportion of transplant failure due to death	***40.8%***
Death Post Transplant Loss	
Sample Size	***4,927***
Death risk after transplant loss (within one year)	***16.6%***
Death risk after transplant loss (second year)	***6.1%***
Waitlist Survival	
Sample Size	***24,333***
Four-year patient survival on the wait list given two-year survival	***87.1%***
Long-term annual death rate on the wait list (Calculated as rate from year 2 to year 4)	***6.7%***
Medicare Costs	
Sample Size	**26,880**
Initial cost (transplant hospitalization)	**$29,885**
Organ Procurement Cost	**$25,300**
Initial cost (first 12 months excluding transplant hospitalization)	**$32,215**

First year cost of transplantation	**$87,400**
Maintenance cost post-transplantation (months 12-24)	**$13,749**
Cost first year following transplant loss	**$134,930**

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Figure 1. Markov model comparing current immunosuppression coverage vs. extended lifetime coverage with associated outcomes, in terms of quality adjusted life years (QALYs) and cost. Abbreviations: p(DWF), probability of death with a functioning graft; p(RTD), probability of return to dialysis.

Figure 2. Projected Patient and Graft Survival with lifetime Immunosuppression Coverage vs. Existing 3-year Coverage. Patient survival (solid), projected over 20 years, was estimated at 55.4% and 61.8% for current coverage (black) and lifetime coverage (grey), respectively. Graft survival (dashed), was estimated at 38.6% and 47.6% for current coverage and lifetime coverage, respectively.

Figure 1.

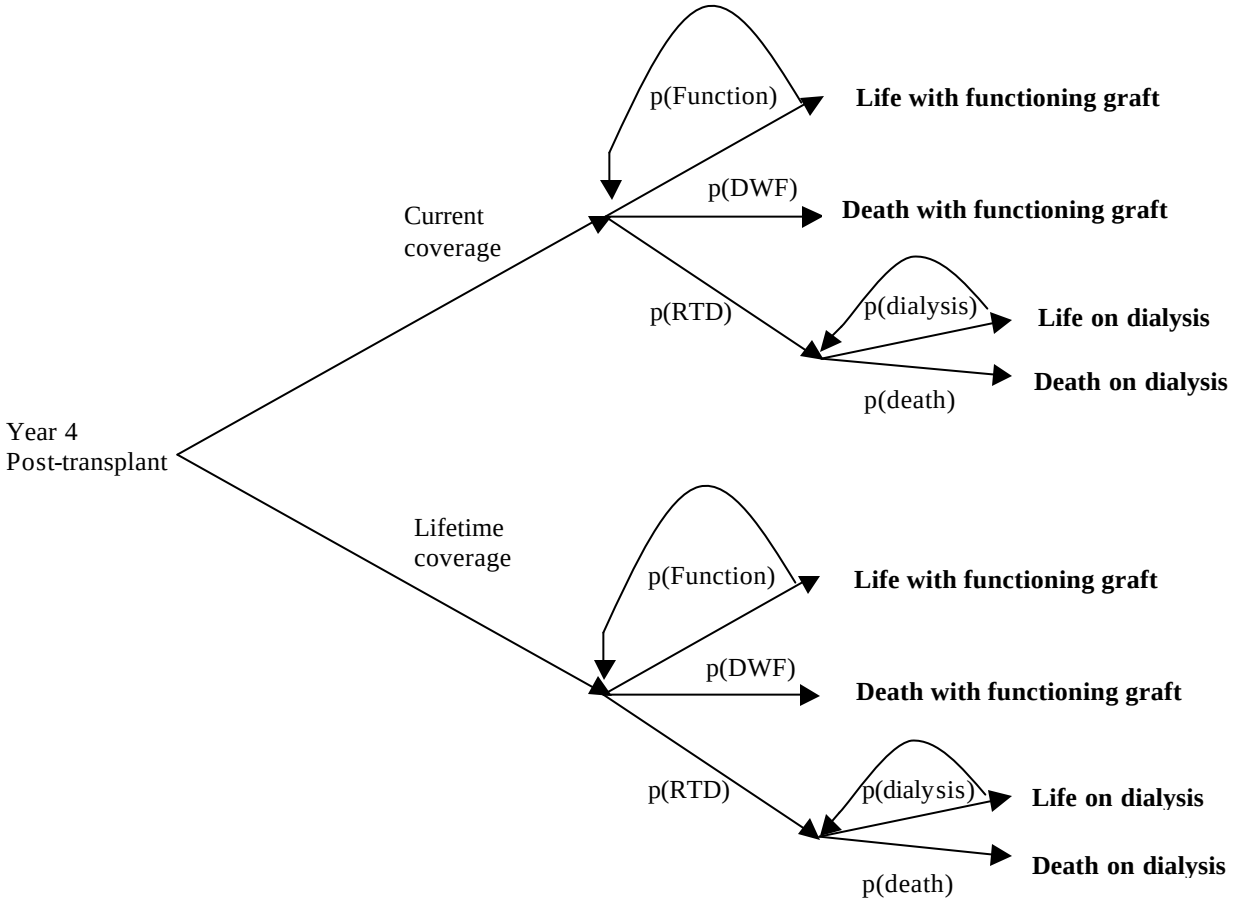
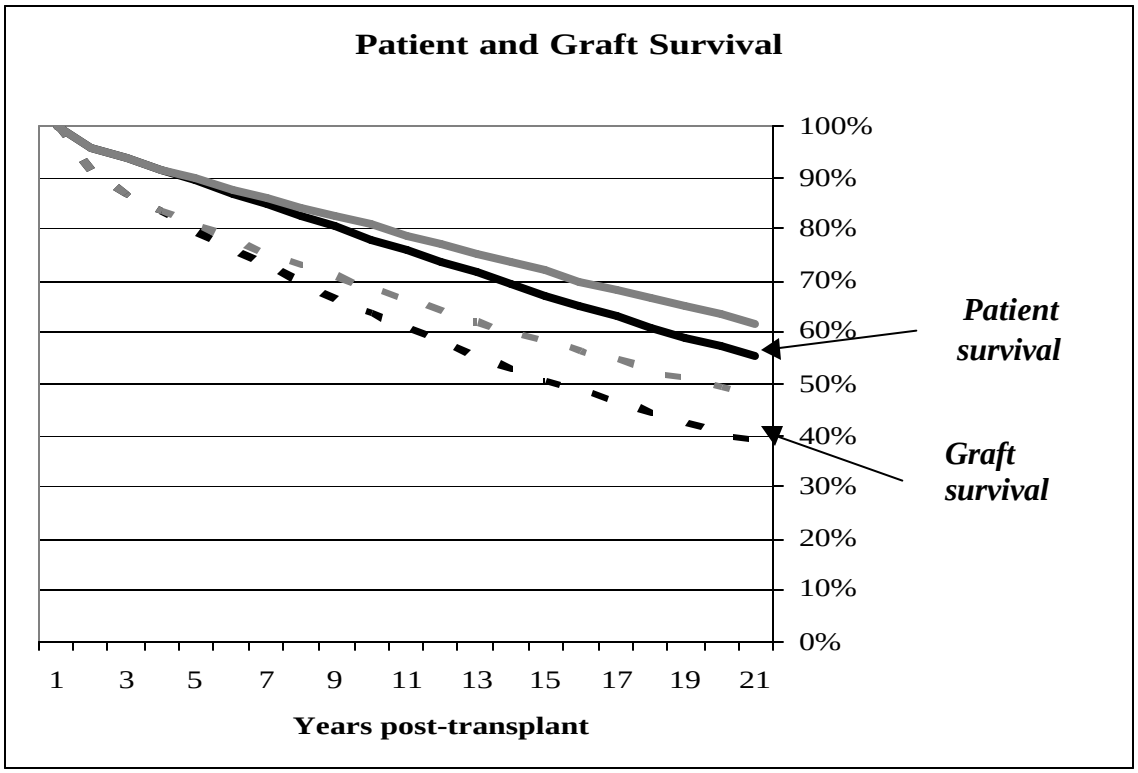

Year 4
Post-transplant
Current
coverage
p(Function)
Life with functioning graft
p(DWF)
Death with functioning graft
p(RTD)
p(dialysis)
Life on dialysis
Death on dialysis
p(death)
Lifetime
coverage
p(Function)
Life with functioning graft
p(DWF)
Death with functioning graft
p(RTD)
p(dialysis)
Life on dialysis
Death on dialysis
p(death)

Figure 2.


Patient and Graft Survival
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
1
3
5
7
9
11
13
15
17
19
21
Years post-transplant
Patient survival
Graft survival