Cost Implications of New National Allocation Policy for Deceased Donor Kidneys in the United States

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Background. In December 2014, a new national deceased donor kidney allocation policy was implemented, which allocates kidneys in the top 20% of the kidney donor profile index to candidates in the top 20% of expected survival. We examined the cost implications of this policy change. **Methods.** A Markov model was applied to estimate differences in total lifetime cost of care and quality-adjusted life years (QALY). **Results.** Under the old allocation policy, average lifetime outcomes per listed patient discounted to 2012 US dollars were US $342 799 and 5.42 QALY, yielding US $63 775 per QALY gained. Under the new policy, average lifetime cost was reduced by US $2090 and lifetime QALYs increased by 0.03. Thus, the new policy improved on the old policy by producing more QALYs at lower cost. The present value of total lifetime cost savings from the policy change is estimated to be US $271 million in the first year and US $55 million in subsequent years. The higher transplant rates and allograft survival expected for candidates in the top 20% of expected survival would decrease costs by reducing time on dialysis. Most cost savings are expected to accrue to Medicare, and most increased access to transplant is expected in private payer populations. **Conclusions.** The new allocation policy was found to be dominant over the old policy because it increases QALYs at lower cost.

(*Transplantation* 2016;100: 879–885)

In December 2014, a new allocation policy was implemented by the Organ Procurement and Transplantation Network (OPTN).[1] Two major goals of the new policy are to reduce disparities in access to transplant and to align expected survival of the allograft with expected survival of the recipient. Understanding the effects of these changes on cost is obviously important.

The new policy incorporates changes in key factors that affect patient survival and transplant rates, including candidate years on dialysis, candidate sensitization, donor quality, and estimated posttransplant survival (EPTS). A feature of the new policy that will potentially affect such change is candidate risk stratification based on EPTS. Candidates in the top 20% of the EPTS distribution will receive priority for offers of kidneys in the top 20% of organ quality, as measured by the kidney donor profile index (KDPI).[1] Factors considered in the EPTS include candidate age, dialysis duration, prior solid organ transplant, and diabetes status, which directly or indirectly affect patient survival and return to dialysis. Factors in the KDPI include donor age, height, weight, ethnicity, history of hypertension and diabetes, cause of death, serum creatinine level, hepatitis C status, and donation after circulatory death status. Additionally, candidates with high calculated panel-reactive antibodies (CPRA) will be prioritized.[1]

Based on the simulation data, the distribution of kidneys did not change substantively by candidate race, primary cause of disease, or regional sharing. Candidates with CPRA greater than 20%, with blood type B, and aged 18 to 49 years were relatively more likely to undergo transplant under the new allocation system.[1] Pediatric candidates receive priority over adult candidates in each category, except for candidates with CPRA 98% or greater, though the simulation projected a slight decline in pediatric transplants. The simulation showed increases in projected average median allograft years of life compared with current policy (9.07 vs 8.82 years).

Received 13 July 2015. Revision received 2 November 2015.

Accepted 2 November 2015.

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The authors declare no funding or conflicts of interest.

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J.M.S., M.A.S., S.K.G., N.S., and J.J.S. participated in research design, writing of the article, performance of the research, and data analysis. B.L.K. and A.K.I. participated in research design, writing of the paper, performance of the research.

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This work was conducted under the auspices of the Minneapolis Medical Research Foundation, contractor for the Scientific Registry of Transplant Recipients, as a deliverable under contract no. HHSH250201000018C (US Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation). As a US Government-sponsored work, there are no restrictions on its use. The views expressed herein are those of the authors and not necessarily those of the US Government.

ISSN: 0041-1337/16/10004-879

DOI: 10.1097/TP.0000000000001057

The lifetime costs of dialysis and kidney transplant are vastly different,[2-4] and payment for these therapies comes from different payers. Any systematic change in the current rates of maintenance dialysis and kidney transplant can potentially alter costs, overall, and for the different providers. Improvements in transplant access would be expected to decrease costs due to shorter time on dialysis and higher transplant rates. Conversely, if the new policy resulted in fewer transplants performed or longer dialysis time, costs may rise. Changes in transplant recipient characteristics, such as recipient age and CPRA, can affect costs because of their effect on graft survival. Younger recipient age would be expected to decrease costs because of improved graft survival and less need for return to dialysis; conversely, higher rates of transplant among sensitized candidates may lead to increased costs.

In this study, we describe the expected cost implications of the new allocation policy.

MATERIALS AND METHODS

Study Population

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of OPTN, and has been described elsewhere.[5] Data on transplant candidates are submitted to OPTN by transplant centers at the time of wait listing and at the time of transplant. The OPTN performs audits on data elements used in allocation. The SRTR receives monthly snapshots of the OPTN database directly from OPTN, at which point SRTR incorporates supplemental data from the Social Security Administration Death Master File and the Centers for Medicare & Medicaid Services to verify endpoints, such as death and return to dialysis. The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

All kidney transplant candidates on the kidney and kidney-pancreas waiting lists from January 1, 2010, to December 31, 2010, and any deceased donor kidneys offered for transplant during this period were considered. The EPTS was calculated for each candidate at the latter of listing date or January 1, 2010. The EPTS thresholds for determining whether a candidate was in the top 20% of survival were based on the national pool of period prevalent kidney waitlist candidates between January 1, 2007, and December 31, 2009, and were calculated within blood type. The KDPI for each kidney allograft was calculated based on the national pool of kidney donors between January 1, 2007, and December 31, 2009.

Modeling Approach

The modeling approach was 2-pronged: first, simulations were performed using the kidney-pancreas simulated allocation model (KPSAM),[4] a computer simulation program used routinely by the OPTN Kidney Committee to assess policy proposals. Cumulative incidence curves of these outcomes were then converted to transition probabilities for a Markov model. The Markov model estimated differences in cost of care and quality-adjusted life years (QALY) between the former and new policies.

The KPSAM simulates waitlist activity, organ offers and acceptance, and posttransplant outcomes between January 1, 2010, and December 31, 2010, under a given organ allocation sequence. Two simulations were performed, 1 to model actual 2010 waitlist and transplant activity, and the other to model the new kidney allocation policy if it had been in place in 2010. Although results are shown alongside 2010 actual data, it is advisable to directly compare results of the 2 simulations with each other rather than with actual 2010 data, because the KPSAM is limited in its ability to replicate reality. Because crucial assumptions, most importantly that of independent random sampling, are not met in the KPSAM, statistical tests of significance were not possible; rather, each simulation was repeated 10 times to provide a measure of variability. Each replication used a different permutation of organ arrival times and a different random number to determine organ offer acceptance. Because the variability in the 10 replications comes only from a random reordering of the organ allocation dates and the use of a random number in organ acceptance, performing more replications yields diminishing returns.

More information about the KPSAM and these simulations can be found in Israni et al.[1]

Posttransplant outcomes included patient death with function, return to dialysis, death on dialysis, relisting, and retransplant. Waitlist candidates who undergo transplant in KPSAM are assigned a graft failure date and either a death date or a relisting date (whichever is estimated to occur first). These dates are generated using several Cox proportional hazards models, which are adjusted for multiple candidate and donor factors. These models were developed using historical waitlist and transplant data.[6] The following factors were adjusted for in the waitlist and posttransplant survival models: candidate age, diagnosis, body mass index, diabetes, kidney versus kidney-pancreas candidate, diagnosis, years on dialysis, preemptive listing, prior solid-organ transplant, peak panel-reactive antibodies, albumin, and several interactions: candidate age by waitlist organ (kidney vs kidney-pancreas), body mass index by waitlist organ, panel-reactive antibodies by waitlist organ, albumin by waitlist organ, preemptive listing by waitlist organ, candidate age by preemptive listing, and previous solid-organ transplant by waitlist organ.

In addition, the posttransplant survival models were adjusted for donation after circulatory death kidney, local/nonlocal kidney, donor age, donor cytomegalovirus status, donor hypertension, donor weight, donor cause of death, expanded criteria donor, HLA mismatches, and 1 interaction: candidate age by donor age.

Cumulative incidence curves of death on the waiting list, transplant on the waiting list, transplant to death with function, transplant to dialysis, dialysis to death, and dialysis to retransplant were generated using the predicted graft failure, relisting, and death dates from KPSAM. Transition state probabilities were then derived from these curves.

Markov Model Using Output From KPSAM

For readers unfamiliar with health economics and quality-of-life studies, the works of Birkmeyer and Liu[7] and Whiting[8] are useful. Quality of life was measured by QALYs, a method commonly used in health economics modeling. The QALYs are accepted as averages of a population's experience in a certain state (ie, on dialysis). A Markov model was used to

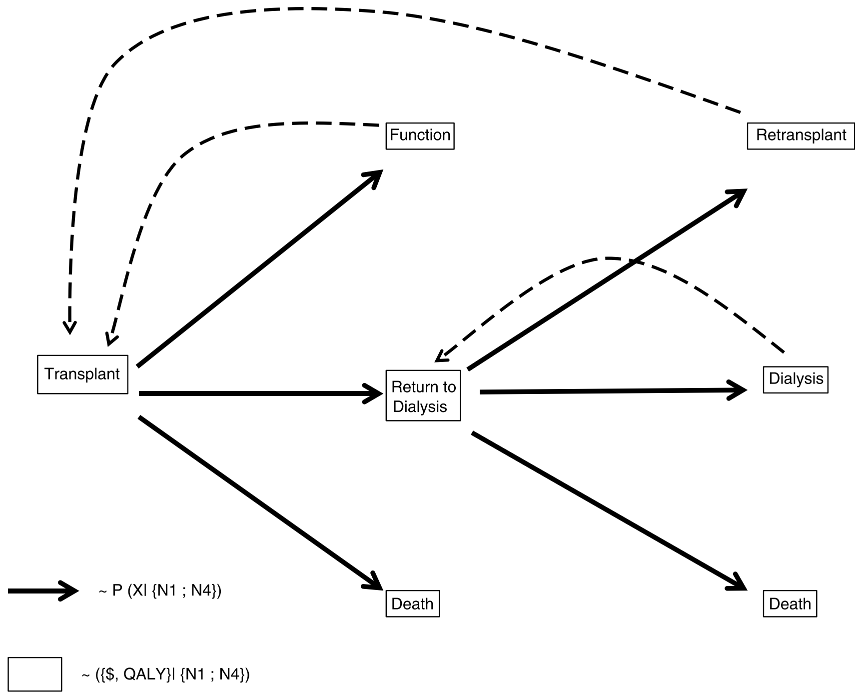

FIGURE 1. Tree diagram of the Markov model. ~ P (XI {N1 ; N 4}) represents transition probabilities between states from KPSAM for the old and new allocation systems. ~ ({$, QALY}I {N1 ; N 4}) represents outcome values ($, QALY) for states. The Markov cycle length was 1 year.

estimate differences between the existing and new policies in total lifetime fiscal cost of care and QALY. The cumulative incidences of waitlist and transplant outcomes were extracted from the KPSAM for the 2 simulations; outcomes were transplant after listing, death on the waiting list, posttransplant return to dialysis, posttransplant relisting, and posttransplant death with and without function. Incidence was calculated separately for candidates in the top 20% and bottom 80% of EPTS.

Figure 1 presents a tree diagram of the model. The pretransplant and postgraft-failure dialysis models were identical except for the addition of return-to-dialysis transition cost and mortality impacts. The Markov cycle length was 1 year, with a 20-year time horizon. Half-cycle correction was used.

Costs associated with each state were taken from previous studies of linked OPTN and Medicare data and have been described elsewhere.[2,9-11] In addition, the weighted costs for each transition and state are described in Table 1. The cost perspective was that of the Medicare end-stage renal disease (ESRD) system. Because organ acquisition costs are not available in Medicare claims data, an estimated US $28 000 in organ acquisition cost was added to the average cost of transplant. We chose this as a representative standard acquisition cost fee; because there was no change in the total number of transplants performed under the old and new systems, we considered the assumption of an unchanged fee reasonable.

Cost differences for states were based on average age and differences in use of expanded criteria donors in the 2 simulations. These differences were used to adjust expected costs based on the results of the source studies. All costs are expressed in 2012 dollars adjusted for inflation using the medical component portion of the consumer price index.[12] Utility measures for the calculation of QALYs were drawn from a study of the relative quality of life with a functioning graft compared with dialysis.[13] The discount rate was assumed to be 3%.

RESULTS

Simulation Results of New Kidney Allocation Policy: Study Population

The results of the simulations of the new kidney allocation policy have been previously described.[1] Briefly, simulations showed an average of 11 599 (minimum, 11 538; maximum,

TABLE 1.
Cost comparison of candidates in the top 20% and bottom 80% of life expectancy

	Life expectancy status	
Costs	Top 20%	Bottom 80%
Transplant cost	US $55 457	US $57 965
Transplant year 1	US $32 896	US $42 134
Transplant year 2 and after	US $14 236	US $16 594
Year of return to dialysis	US $136 338	US $142 516
Maintenance dialysis pretransplant or posttransplant	US $38 616	US $39 011
Incremental cost of death	US $59 106	US $64 494

11 681) kidney and kidney-pancreas transplants under the new allocation policy, compared with an average of 11 531 (minimum, 11 463; maximum, 11 586) under the old policy. The average median life span and graft-years of life were longer for transplant recipients under the new policy. Simulations predicted a 2.8% increase in average median allograft years of life and a 7.0% increase in average median life-years per transplant. Candidates with CPRA greater than 20%, with blood type B, and aged 18 to 49 years were more likely to undergo transplant. Characteristics varied substantially between transplant recipients in the top 20% and bottom 80% of life expectancy (Table 2). Compared with recipients in the bottom 80%, recipients in the top 20% were more likely to be aged younger than 50 years, be of Hispanic ethnicity, be preemptively listed or have dialysis duration less than 5 years, have private insurance or Medicaid rather than Medicare at listing, and be nondiabetic with glomerulonephritis or cystic kidney disease as primary causes of kidney failure.

Cost-Effectiveness Comparison of New and Old Kidney Allocation Policies

Under the old allocation policy, average values per patient from listing through 20 years postlisting discounted to 2012 US dollars were US $342 799 and 5.42 QALYs, for a cost-effectiveness ratio for transplant versus dialysis of US $63 775 per QALY gained (Table 3). Under the new policy, average lifetime cost was reduced by US $2090 and QALYs were increased by 0.03 to US $340,709 and 5.45, yielding a cost-effectiveness ratio for transplant versus dialysis of US $62 515. Thus, the new policy was found to strongly dominate the old policy, because QALYs are increased at lower cost.

Cost and Transplant Access

Figure 2 compares the cumulative incidence of transplant under the old and the new policies over 15 years. As expected, waitlisted candidates in the top 20% of life expectancy were more likely to undergo transplant and to do so earlier under the new policy; approximately 50% of these candidates underwent transplant by 3.2 years after listing, compared with almost 4.5 years under the old policy. Candidates in the bottom 80% of life expectancy were generally less likely to undergo transplant under the new policy; the median time to transplant increased from 5.3 years under the old policy to 7.8 years under the new policy. An early increase in the transplant rate for these candidates was driven

TABLE 2.

Characteristics of recipients in simulations of old policy and new policy, by status in the top 20% or bottom 80% of life expectancy

	Life expectancy status					
	Top 20%			Bottom 80%		
Characteristics (%)	Waiting list 2010	Old policy (Simulated)	New policy (Simulated)	Waiting list 2010	Old policy (Simulated)	New policy (Simulated)
Age, y						
<18	6.5	21.0	13.8	0.00	0.03	0.03
18-34	45.6	39.9	44.5	2.0	1.5	1.7
35-49	46.8	38.0	40.4	22.6	21.3	21.3
50-64	1.2	1.1	1.3	53.2	53.2	53.8
≥65	0.0	0.0	0.0	22.1	24.0	23.1
Race						
Black	34.1	34.5	34.4	33.2	33.9	35.2
Hispanic	19.5	19.2	19.1	17.1	13.1	13.4
White	37.9	39.7	39.7	41.1	45.7	44.4
Other/unknown	8.5	6.6	6.8	8.6	7.3	7.0
Dialysis duration, y						
None	32.5	29.4	27.8	24.3	24.4	21.2
<5	63.7	66.6	67.6	68.1	67.5	68.1
5-10	3.3	3.7	4.1	5.8	6.3	8.2
≥10	0.50	0.34	0.50	1.8	1.8	2.6
Payer at listing						
Private	47.2	43.4	43.0	41.1	42.8	39.9
Medicare	37.6	40.5	41.9	51.0	51.6	54.1
Medicaid	14.2	15.2	14.4	7.0	5.0	5.5
Other/unknown	1.0	0.89	0.80	0.9	0.65	0.53
Primary cause of disease						
Diabetes	0.24	0.07	0.12	37.5	30.6	31.9
Hypertension	24.2	18.1	21.1	25.4	27.1	27.2
Glomerulonephritis	28.4	28.2	27.9	11.8	13.9	13.1
Cystic kidney disease	6.9	11.3	9.6	1.2	1.3	1.5
Polycystic kidney disease	8.0	7.0	7.6	6.7	8.8	7.8
Other/unknown	32.3	35.3	33.6	17.3	18.3	18.5

TABLE 3.

Cost-effectiveness comparison of new and old kidney allocation policies

	Lifetime average discounted cost	Lifetime average discounted QALYs	Cost-effectiveness ratio, QALY	Cost-effectiveness, old/new
Old policy	US $342 799	5.42	US $63 775	
New policy	US $340 709	5.45	US $62 515	
Difference	–US $2090	0.03	–US $1260	
Cost-effectiveness, old/new				New policy is dominant

by the change in backdating of waiting time to the date of first dialysis; under the new policy, candidates received an allocation point for every year of dialysis before registration on the waiting list, and prelisting dialysis duration was more likely to have been longer for candidates in the bottom 80%. However, the incidence curves reached parity at approximately 2.5 years postlisting (Figure 2), after which candidates in the bottom 80% underwent transplant at a lower rate under the new than under the old policy. Candidates in the top 20% lived longer while on dialysis, and thus accumulated more lifetime medical expenses related to dialysis. Thus, cost savings were due to improved access to transplant, shorter time on dialysis, and higher transplant rates for these candidates. Allograft survival was better for candidates in the top 20% than for candidates in the bottom 80%, as evidenced by a lower rate of return to dialysis (Figure 3).

Medicare Versus Private Payer

Increased access to transplant for candidates in the top 20% of life expectancy is expected to increase private insurance coverage of kidney transplant, because these candidates are more likely to be covered by private insurers and to undergo transplant before the end of the 30-month coordination of benefits (COB) period (Table 2). Reduced access for candidates in the bottom 80% is expected to increase Medicare coverage of dialysis, because these candidates will spend more time on dialysis after the end of the COB period. Less conversion to Medicare primary coverage at the end of the COB period for candidates in the top 20% will also reduce payments to transplant centers for the transplant portion of the Medicare Cost Report by reducing the Medicare fraction of kidney transplant costs.

The value of savings in ESRD care, compared with costs under the old policy, over the 20 years after the first year of the policy change, is expected to be US $271 million during the first year and US $55 million during each subsequent year the policy is in place. The savings are expected to accrue primarily to Medicare, because under the new policy, candidates in the top 20% of life expectancy are more likely to undergo transplant early while they are privately insured, potentially avoiding Medicare until they enroll due to age or graft failure. Medicare savings may exceed total savings, with a small or modest increase in total private payer ESRD costs.

Sensitivity Analysis

A sensitivity analysis was performed of expected per-patient lifetime cost savings considering a 25% increase or decrease in the cost inputs presented in Table 1. There was no effect of varying cost inputs on QALY gains. Each input was varied individually, and the resulting impact on cost savings is presented in a tornado plot (Figure 4). A cost savings was found with each variation. The largest impact on cost savings was for maintenance dialysis for candidates in the bottom 80%, with a high-to-low spread of US $2880, followed by maintenance dialysis for candidates in the top 20%, with a spread of US $2456. Other variations were relatively small. Varying organ acquisition costs by 25% produced a small cost savings range from US $2010 to US $2143. We also considered setting cost assumptions equal for candidates in the top 20% and bottom 80%, which maintained a per-patient cost

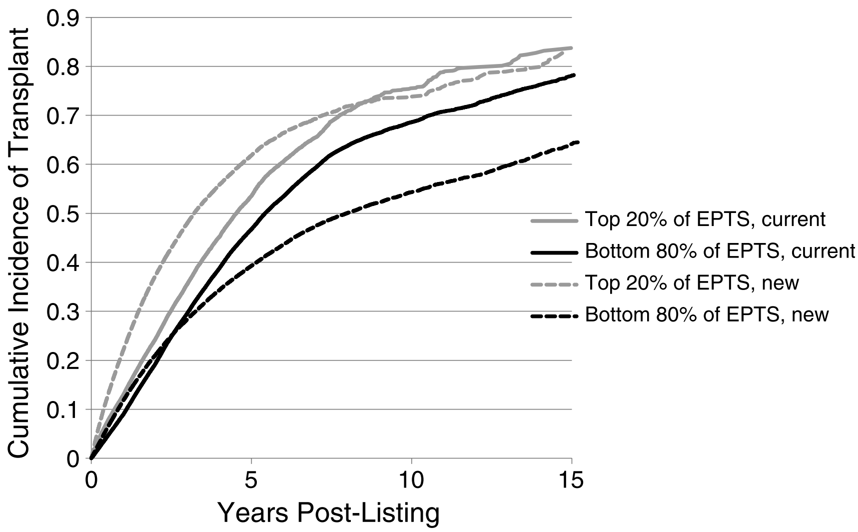

FIGURE 2. Transplant access comparison of candidates in the top 20% and bottom 80% of EPTS under the old and new allocation policies.

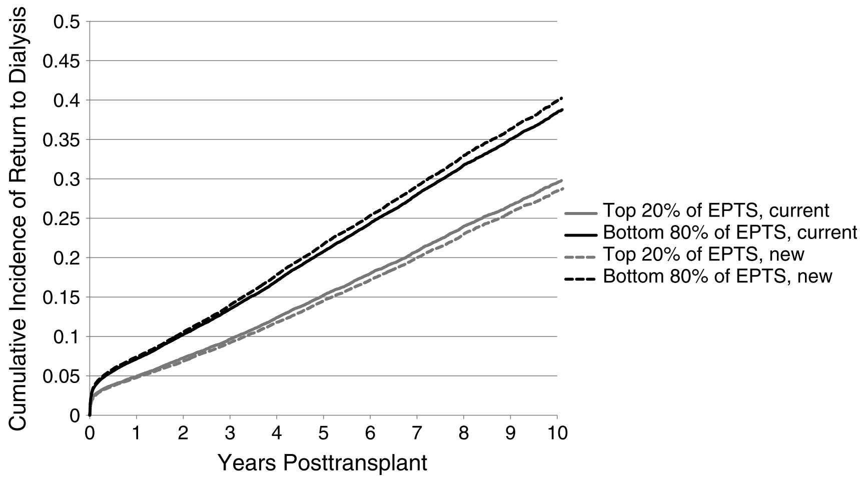

FIGURE 3. Posttransplant return to dialysis comparison of candidates in the top 20% and bottom 80% of EPTS under the old and new allocation policies.

savings reduced to US $1659. Possible effects of reduced living kidney donation due to changes in deceased donor organ allocation were potentially large for both cost savings and QALY gains. Using data from a previous cost-effectiveness analysis of living kidney donation,[3] a 10% reduction in living donation reduced per-patient cost savings to US $1545 and per-patient QALY gain to 0.01. A 25% reduction in living donation reduced per-patient cost savings to US $848 and produced a per-patient QALY loss of 0.03. Finally, a 50% reduction in living donation produced a per-patient loss of US $314 and a per-patient reduction in QALY of 0.1.

DISCUSSION

Changes in organ allocation policy affect transplant economics through changes in transplant volume and access, recipient characteristics, allograft and patient survival, and payer. We examined the effects of the new kidney allocation policy on cost, QALY, and organ utilization. Under the new allocation policy, the average lifetime cost was reduced by US $2090 and lifetime average QALY was increased by 0.03 compared with the old policy. The new policy was found to be dominant because it increases QALYs at a lower cost. The total cost savings are expected to be US $271 million in the first year and US $55 million in subsequent years.

Organ utilization is an important determinant of cost and QALY. Simulations of the new allocation policy resulted in an average of 11 599 kidney and kidney-pancreas transplants compared with an average of 11 531 under the old policy, or an average of 68 fewer kidneys recovered but not transplanted under the new policy. Organ acceptance behavior will be an important factor in the ultimate long-term benefits of the new kidney allocation policy. A novel feature of the new policy is greater sharing of kidneys across all levels of KDPI, but particularly of marginal kidneys with KDPI greater than 0.85. Although kidneys in the top 20th percentile of the KDPI were used to an even greater degree under the new than under the old policy, the percentage of recovered but not transplanted kidneys in percentiles above the 85th percentile increased from 47% under the old to 59% under the new policy. Notably, kidneys in the percentiles above the 85th percentile are mandatorily shared at a regional level for nonzero mismatch offers. This feature of the policy was an attempt to reduce cold ischemic time and improve utilization of marginal kidneys; such kidneys may not have been recovered or transplanted by organ procurement organizations whose local centers were unlikely to accept them under the old policy.[5] Adaptation of acceptance behavior to the new policy, in part through increased awareness of candidates' relative positions on the waiting list, is crucial. The KPSAM was built based on existing organ acceptance patterns. These patterns will likely change under the new policy, which may yield even greater benefits to patients. However, acceptance patterns could change in ways that adversely affect organ utilization and living donation. Careful monitoring of the impact of the new policy on organ acceptance will be important.

Changes in access to transplant affect costs because of the varying costs of dialysis and transplant in different patient populations. Candidates in the top 20% of life expectancy, for example, live longer while on dialysis, and thus accumulate higher lifetime medical expense if they stay on dialysis.

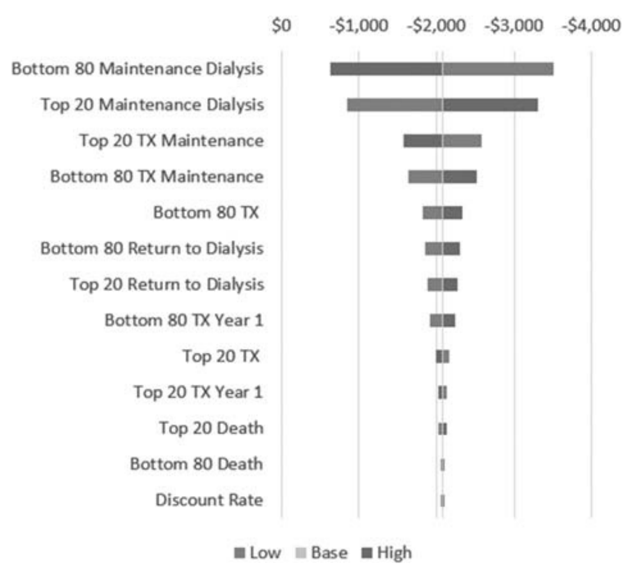

FIGURE 4. Sensitivity analysis of a 25% variation in individual cost inputs. TX, transplant.

Under the new allocation policy, the higher transplant rates expected for these candidates and the resulting shorter dialysis duration lead to cost savings.

The expected improvement in allograft survival under the new allocation policy will decrease costs due to less need for dialysis. Allograft survival is improved in candidates in the top 20% of life expectancy compared with those in the bottom 80%, and rates of return to dialysis are lower. Simulations predicted a 7.0% increase in average median patient life-years per transplant and a 2.8% increase in average median allograft years of life.[1] This corresponds to a composite gain of 9130 life-years of patient survival and 2750 years of allograft survival, assuming 11 000 transplants.

Any systemic alteration in the old rates of dialysis use or of transplant has the potential to redistribute costs among payers. Most cost savings are expected to accrue to the Medicare ESRD system, while most increased access is expected in private payer populations. The increased transplant access for candidates in the top 20% of life expectancy is expected to increase private insurance coverage of kidney transplant because these candidates are more often covered by private insurers. Reduced access for candidates in the bottom 80% is expected to increase Medicare coverage of dialysis. However, less conversion to Medicare primary coverage at the end of the COB period is expected among candidates in the top 20%, coupled with lower payments to centers for the transplant portion of the Medicare Cost Report. The money saved per QALY lost is similar to the cost per QALY on dialysis for waitlisted candidates.

Our study has several limitations. We used results of KPSAM simulations that were used by OPTN to submit the policy for public comment.[1] Modeling future organ acceptance behavior after a large change in allocation policy is beyond the capabilities of KPSAM. Rather, acceptance behavior was treated as constant between the old and the new policies and was modeled from actual 2010 acceptances. We address the economic impact of behavior related to organs recovered but not transplanted, but many other factors remain to be explored, including listing behavior, patient preferences, and the impact of prioritizing high CPRA candidates. Although organ sharing is accounted for via a local/nonlocal organ variable in the posttransplant graft and patient survival models, the cost of shipping organs is not included in our analysis, and this is a limitation. The simulation projected an increase in shared kidneys; if the increase is more than what was estimated, it could reduce the projected cost savings somewhat. However, graft and patient survivals are ultimately the primary drivers of cost and QALYs in the model. Our analysis was found to have limited sensitivity to economic inputs; however, potentially high sensitivity was found to reduce living kidney donation rates. Although early observations after the change in allocation policy do not suggest large reductions in living kidney donation, it is beyond our capabilities to model behavioral changes. Living donation provides large benefits and should be monitored and encouraged.

Twenty years is the standard timeframe used in Markov modeling for transplant. This assumes that the next 20 years of transplant care will be similar to what it is today. The evidence to date supports this conclusion; as seen in the OPTN/SRTR Annual Data Report,[14] the cost of transplant care has been stable over the past decade. Considering the impact of potential changes in cost in the future, our results would be invalidated only if medical care that is more expensive now (dialysis) becomes less expensive in the future, and medical care that is cost-saving now (transplant) becomes more expensive in the future.

Our findings may be generalizable to other areas of health care with similar demand/supply disparity; however, transplantation is unique because organs are human products, and as such cannot be manufactured to meet demand. Therefore, our research is most applicable to bone marrow transplants, tissue transplants, blood transfusions, and other solid-organ transplants. This work may also apply to shortages of drugs and medical supplies due to manufacturing problems.[15]

Anticipated changes in transplant volume and access and recipient characteristics and survival all contribute to the economic impact of the new allocation policy. Organ utilization is a key determinant in the cost savings and QALY gains that can be expected.

ACKNOWLEDGMENTS

The authors thank SRTR colleagues Delaney Berrini, BS, for article preparation, and Nan Booth, MSW, MPH, ELS, for article editing.

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