

The Magnitude of the Health and Economic Impact of Increased Organ Donation on Patients With End-Stage Renal Disease

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Abstract

Objectives. There are several approaches such as presumed consent and compensation for deceased donor organs that could reduce the gap between supply and demand for kidneys. Our objective is to evaluate the magnitude of the economic impact of policies to increase deceased donor organ donation in the United States. **Methods.** We built a Markov model and simulate an open cohort of end-stage renal disease patients awaiting kidney transplantation in the United States over 20 years. Model inputs were derived from the United States Renal Data System and published literature. We evaluate the magnitude of the health and economic impact of policies to increase deceased donor kidney donation in the United States. **Results.** Increasing deceased kidney donation by 5% would save \$4.7 billion, and gain 30,870 quality-adjusted life years over the lifetime of an open cohort of patients on dialysis on the waitlist for kidney transplantation. With an increase in donations of 25%, the cost saved was \$21 billion, and 145,136 quality-adjusted life years were gained. Policies increasing deceased kidney donation by 5% could pay donor estates \$8000 or incur a onetime cost of up to \$4 billion and still be cost-saving. **Conclusions.** Increasing deceased kidney donation could significantly impact national spending and health for end-stage renal disease patients.

Keywords

compensated donation, cost-effectiveness, implied consent, kidney transplant

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Introduction

The United States has a dramatic gap between the supply of and demand for organs for kidney transplantation. For example, in 2018, there were 21,167 deceased-donor kidney transplants (KT), while 38,791 KT candidates were added to the waiting list. Furthermore, 3888 candidates died while on the waiting list. Eighty-four percent of all patients awaiting transplant in the United States are awaiting KT, with most recent data showing 94,845 candidates on the kidney list compared with 113,379 on all organ waiting lists.¹ This discordance in organ supply and demand stems from both low donation and suboptimal organ utilization rates.² The gap in supply and demand leads to significant costs associated with

end-stage renal disease (ESRD) and dialysis, as previous analyses have shown that kidney transplantation leads to cost savings.^{3–16} In 2019, in the United States, Medicare spent \$35.4 billion, or 7.2% of its overall spending, on patients with ESRD.¹⁷

Although kidneys can be transplanted from living donors, only one kidney can be transplanted from a living donor whereas two can be transplanted from a deceased donor. In 2019, 77% of kidneys transplanted

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were from deceased donors.¹ There are several proposed approaches to address low deceased donor donation rates. One approach that has been implemented by several countries worldwide is a presumed consent policy where all deceased persons are presumed to have consented to organ donation unless they have specifically opted out of being an organ donor. This contrasts to current US policy where organ donors opt-in to being an organ donor. A 2009 systematic review examined the impact of presumed consent on organ donation rates and found that presumed consent policies were associated with a 20% to 30% increase in deceased organ donation rates.¹⁸ However, the impact of these policies can be difficult to evaluate since they are observational in nature, and many factors (such as motor vehicle accidents, cerebrovascular causes of death, transplant capacity, gross domestic product per capita, health expenditure per capita, religion, education, public access to information, and a common law legal system) can also confound results. Cognitive psychologists have conducted both online hypothetical experiments and regression analysis of international time series data, demonstrating that presumed consent would increase donation rates.¹⁹ Yet the precise impact that a presumed consent policy would have in the United States is not known. Other approaches may involve implementation of policies to maximize the efficiency of donor organ consent and retrieval in hospitals^{20–22} or financial compensation for families of the decedent (e.g., to help cover funeral expenses).^{22–24} The precise impact of these policies on organ donation is also unknown.

While there are potentially significant societal and ethical barriers toward institution of policies to increase organ donation, the end result would likely increase organ donation and transplantation rates. While this would have a significant impact on improving health outcomes of patients awaiting transplantation, it could also result in significant increased costs in the short term, due to the resource-intensive nature of solid organ transplantation. Over the long term, however, a policy that would increase deceased donor organ transplantations could lead to reduced health care costs, as prior studies have shown that organ transplantation is a cost-saving intervention.^{25–27} This is particularly true in kidney

transplantation, as dialysis for ESRD is a costly, long-term therapy.^{5,6} One study suggests doubling of the number of kidney transplants per year could lead to \$14.1 billion in taxpayer savings per year.⁴

The aim of this study is to quantify the magnitude of the health and economic impact of policy measures aimed to increase organ donation rates on deceased donor kidney transplantation for individuals with ESRD in the United States.

Methods

We compared the health and economic outcomes between an increase in the annual probability of deceased donor organ transplant and the status quo (an opt-in organ donation consent policy) in the United States. We used an age-structured deterministic Markov state transition model of the population of ESRD patients awaiting kidney transplants to make projections for how these policies would affect the health and costs for these patients (Supplemental Exhibit 1).

Patients entered the model as dialysis patients on the waitlist for KT. They remained on dialysis, received a KT, were removed from the waitlist, or died. The KT was from either a living or deceased (brain or cardiac death) donor. If the patient received a KT, the patient could survive with the transplant, experience graft failure and transfer back to dialysis, or die. The rates of transplant and removal from the waitlist vary based on time on the waitlist,²⁸ so the first three years on the waitlist were modeled as separate health states. Costs and mortality are substantially lower in the second and subsequent years following transplant, so they were modeled as separate health states. Mortality is also higher based on age. Because of this, as individuals spend time on the waitlist on dialysis, mortality increases. Model parameter values are in Supplemental Exhibit 2. The cycle length of the model is 1 year.

We simulated patient progression by modeling increases in organ availability for kidney transplantation over their lifetimes. The deterministic Markov model simulates a closed cohort of individuals at various ages. These results are then aggregated together for the individuals currently on the waiting list as well as for all future additions to the waitlist (discounted) to get the overall results for an open cohort of individuals (see Supplemental Exhibit 3). We assumed the numbers of new people by age added to the waitlist followed the same patterns to current waiting list additions (Supplemental Exhibit 7). We did not model the complexities of the organ matching system but assumed deceased donor transplantation rates would change by

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various percentages. All analyses were conducted using TreeAge Software (Williamstown, MA)²⁹ and Microsoft Excel (Redmond, WA).³⁰

Potential Impact of Policies on Deceased Organ Donation

Our base estimates of the potential impact of policies on transplantation rates are informed by a systematic review of presumed consent by Rithalia et al.¹⁸ This review included eight studies comparing European and OECD countries with presumed consent to those without. It also included five studies comparing the effect before and after introducing the presumed consent system of three countries: Austria, Belgium, and Singapore. Their review suggested the institution of a presumed consent policy was associated with an increase in deceased organ donations in the range of 21% to 30%. However, individual studies reviewed reported a variety of changes in donation rates (see supplement materials for additional details).

Because of the uncertainty in the change in donation rates that might be seen in the United States with a presumed consent organ donation policy, we assumed that the policy would increase the annual probability of deceased donor transplants to ESRD patients by 5% in the base case. We increased this to 25% in sensitivity analysis to explore the impact of uncertainty in this impact of this policy. We assumed the number of living donors did not change in the base case, but altered this in sensitivity analysis as there is concern that increases in deceased donor organ transplantation rates may reduce the rates of donation from living donors.^{31,32}

End-Stage Renal Disease and Transplant Transition Rates

The model simulated the progression of kidney disease for patients on dialysis and with a kidney transplant. Annual transition probabilities for the model came from published studies.^{10,28,33–35} Data from the United States were used as base case parameters, while data from other countries were used for ranges in sensitivity analysis (Supplemental Exhibit 2).

Mortality

Mortality on dialysis and following transplantation is by age and came from the US Renal Data System (USRDS) annual report¹⁷ (Supplemental Exhibit 4).

Cost

Annual costs were set for dialysis patients and transplant patients based on data by age from the USRDS annual report.¹⁷ We averaged the per-person costs for each of the categories reported in the USRDS for 2010 to 2014 and adjusted them for inflation to year 2020 dollars using the Gross Domestic Product deflator³⁶ (Supplemental Exhibit 5).

Utility

Utilities for dialysis and transplantation were derived from a review of the existing literature (Supplemental Exhibit 2 and Supplemental Exhibit 6).

Cohort of Patients

Our analysis examined an open cohort of ESRD patients who started on or entered the waiting list over a lifetime time horizon, where every patient is simulated in the model until death occurs or the patient's age is 100 years old. The initial cohort of patients on dialysis was based on a cohort of patients from 2014 as reported in the 2016 USRDS Annual Data Report.¹⁷ The patients were grouped into 17 age groups (primarily grouped in 5-year age groups), with a final age group of 75 + . We assumed waitlist additions were constant each year based on average waitlist additions observed from 2010 to 2014 while avoiding double-counting individuals listed for subsequent transplant who had already been modeled in prior year cohorts¹⁷ (see Supplemental Exhibit 7 for details).

Outcomes

The model provided several outcomes, including number of kidney transplants, years on dialysis, total costs, life years lived, and quality-adjusted life years (QALYs) experienced.

All costs were expressed in 2020 US dollars, and all costs and future QALYs were discounted at an annual rate of 3%.³⁷ We used the perspective of the health system including health costs, but not other societal costs of diseases.

Sensitivity Analysis

We conducted several sensitivity analyses. We first evaluated changes to the cohorts under analysis: 1) to measure medium-term impacts of the policy change, we examined both the initial cohort on the waiting list and additions to the waiting list, but only followed this cohort over 20 years (Supplemental Exhibit 8); 2) we examined the

Table 1 Base Case Result for the Open Cohort

	Status Quo	Increase in Deceased Organ Transplantation	
		5% (Base Case)	25%
Cost outcomes (US dollars, millions)			
Total cost	637,833	633,133	616,353
Incremental cost savings ^a	—	4700	21,480
Transplant cost	83,100	84,850	91,208
Dialysis cost	421,087	411,886	378,747
Health outcomes			
Total QALYs	7,179,376	7,210,246	7,324,512
Incremental QALYs gained ^a	0	30,870	145,136
Number of transplants	683,047	696,606	745,729
Years on dialysis	5,555,387	5,428,297	4,974,272
Years on dialysis waitlist	3,385,719	3,288,964	2,947,842
Years on dialysis after graft failure	1,104,389	1,114,679	1,144,472

QALY, quality-adjusted life year.

^aCompared to status quo.

impact of the policy on only the cohort of patients currently on dialysis over their lifetimes (i.e., closed cohort).

We conducted one-way sensitivity analyses to evaluate the relative importance of individual parameter values to the overall conclusions. For most analyses, we disaggregate costs and QALYs; however, in this one-way sensitivity analysis, we combined the dollars saved with the QALYs gained into a single measure of net monetary benefit valuing each QALY at \$100,000, which health economists suggest may be a reasonable value.³⁸

We then analyzed three possible scenarios: 1) the impact on the cost-effectiveness of the deceased donor policy if it also led to a decrease in living kidney donation rates; 2) the implementation of the deceased donor policies adds billions of dollars in administrative costs for policy implementation, administration, or for payments to donor families; 3) the impact of per-donor payment policies on cost-effectiveness. In our base analysis, we assumed zero administrative costs or per-donor costs to implement a policy that increases deceased donation.

Finally, we varied parameters simultaneously in a probabilistic sensitivity analysis using Monte Carlo simulation with 10,000 iterations (see Supplemental Exhibit 9 for distributions). In the probabilistic sensitivity analysis, we examined the distribution of cost savings with a 5% increase in donation rates compared to the status quo.

Results

Model Validation

The model cohort predicts numbers of deceased donors slightly higher than those seen from the Organ Procurement

and Transplantation Network (Supplemental Exhibit 10). In addition, our model projects that each additional transplant leads to average savings of \$490,276 and a gain of 2.40 QALYs. The QALYs gained are broadly consistent with other literature on the benefit of kidney transplantation, and the cost savings are higher than average^{5–14,16,39–41} (Supplemental Exhibits 11 and 12).

Base Case Analysis

When compared with the status quo, a policy increasing deceased donor organ transplants by 5% would save \$4.7 billion, and gain 30,870 QALYs over the lifetime of an open cohort of patients on dialysis and on the waitlist for kidney transplantation (Table 1). These savings are due to the increase in the number of transplants and corresponding decrease in patient-years on dialysis. When the increase in donation is 25%, the costs saved are over \$21 billion, and 145,136 QALYs are gained.

Sensitivity Analysis

Twenty-Year Time Horizon. When the analysis is restricted to 20 years, \$1.5 billion is saved and 6651 QALYs are gained. Increasing the rate of organ donation to 25% drastically changes numbers of transplants and saves \$6.6 billion and gains 29,550 QALYs when compared to the status quo (Table 2).

Closed Cohort. When only evaluating the impact on individuals currently on the waiting list, \$448 million is saved and 2806 QALYs are gained. Increasing the rate

Table 2 Twenty-Year Time Horizon Results for the Cohort

	Status Quo	Increase in Deceased Organ Transplantation	
		5% (Base Case)	25%
Cost outcomes (US dollars, millions)			
Total cost	224,714	223,196	217,567
Incremental cost savings ^a	—	1518	7148
Health outcomes			
Total QALYs	1,794,647	1,801,298	1,824,197
Incremental QALYs gained ^a	—	6651	29,550

QALY, quality-adjusted life year.

^aCompared to status quo.

of organ donation to 25% saves \$2.0 billion and gains 13,202 QALYs when compared to the status quo (Supplemental Exhibit 13).

One-Way Sensitivity Analysis. The tornado analysis shows which variables have the largest impact on the results in terms of total benefit (5% increase) over the status quo measured in dollars using a willingness-to-pay of \$100,000. The top three variables are (in order): the utility of dialysis patients on waitlist, the utility of transplant patients after year two with organ from donation after brain death, and the costs of dialysis patients on the waitlist (Supplemental Exhibit 14). In all cases, the net monetary benefit is still over \$3 billion.

Scenario Analyses. We also analyzed scenarios where the impact of the policy might have a different impact on both living and deceased donor rates. In the first scenario analysis, we examined how a policy to increase deceased organ donation might fare if it caused a reduction in living donation rates. We found that if living donor rates declined by 20%, a policy that increased deceased donation rates by 5% would still be cost-effective (Supplemental Exhibit 15).

In the second scenario analysis, we examined how cost-effectiveness would be affected by potential startup implementation costs and varying deceased transplantation rates (Figure 1). If donation rates increased sufficiently, startup implementation could cost billions of dollars and still remain cost-effective or cost-saving. For example, if implementation costs were \$4 billion all up-front and resulted in increased donation rates by 5%, it would remain cost-saving.

In the third scenario analysis, we examined what payments could be made to donors for the program to still be cost-effective at various levels of willingness-to-pay

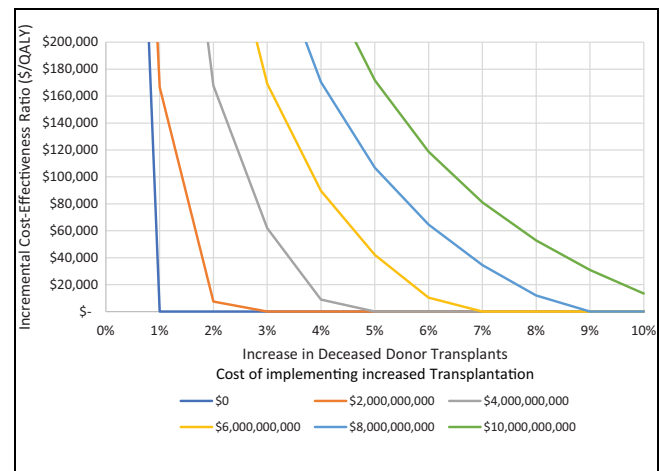


Figure 1 Impact of increase in deceased donor donations and fixed cost of implementing policy on cost-effectiveness. If the line intersects the x-axis, the policy to increase donation is cost-saving.

per QALY gained (Figure 2). If donation rates increased by 5%, payments could be \$7903 per donor and the program would still be cost-saving. If payments were \$25,159 per donor but the program induced an increase in donations by 10%, the program would have an incremental cost-effectiveness ratio of \$100,000 per QALY gained.

Probabilistic Sensitivity Analysis. The results of the probabilistic sensitivity analysis show a policy increasing deceased donation rates by 5% is highly likely to have cost savings in the range of \$3.5 to \$6.5 billion (Supplemental Exhibit 16). The policy was always cost-saving across the sensitivity analysis (Supplemental Exhibit 17).

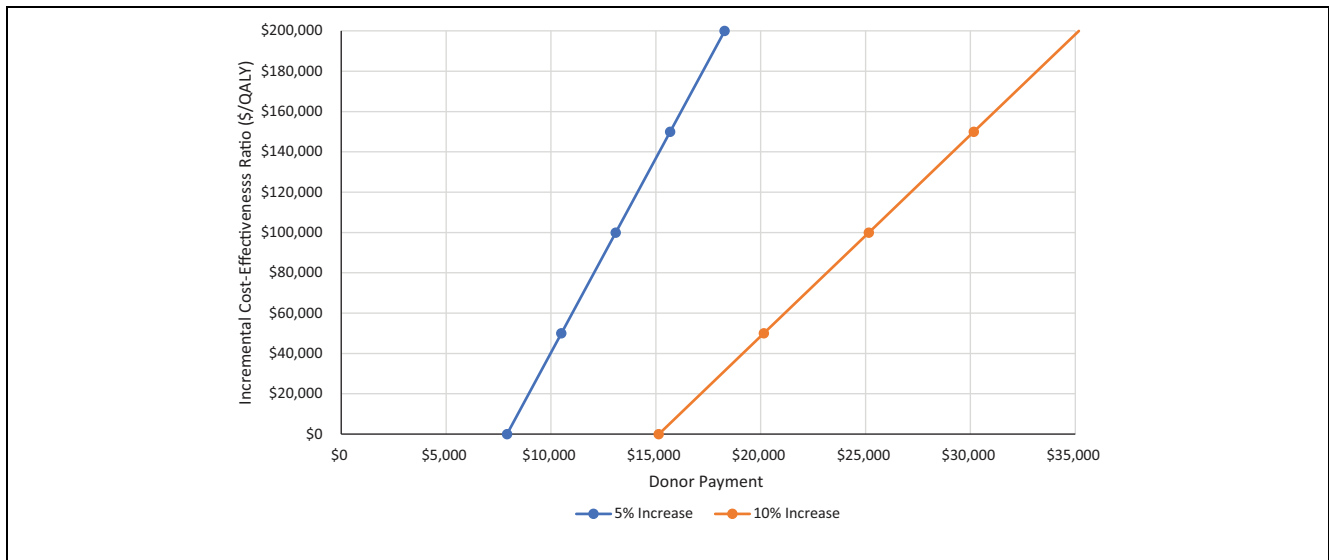


Figure 2 Impact of increase in deceased donor transplantation and donor payment on cost-effectiveness. If the line intersects the x-axis, the policy to increase donation is cost-saving.

Discussion

Our analysis shows that a policy increasing deceased donor organ transplants by a modest amount could lead to large improvements in health for ESRD patients and lead to billions of dollars of savings for the health care system over the long term. Increases in donation rates of 5% would lead to \$4.7 billion in cost savings. Alternatively, if the policy is examined over a shorter time horizon of 20 years, a 25% increase in donations would lead to \$7.1 billion in savings. Our findings are robust to changes in our modeling assumptions. These findings are similar to those in other studies^{3-14,16,39} (Supplemental Exhibit 11).

While our analysis shows the health and economic impact of a policy increasing deceased organ donation, there are many practical concerns with implementing such policies in the United States. Presumed consent and compensated deceased organ donation policies are controversial. First, the public would have to be educated about this new policy. For a presumed consent policy, national databases would need to be set up to record those who opt-out. For a compensated donation policy, funds and distribution procedures would need to be established. If this policy increased deceased donations, the system of procuring and transplanting organs could require reconfiguration to accommodate the increased volume of transplants (e.g., health care workers, transplant facilities). We did not include the costs of public education and possible health care systems changes in

our model; however, these costs would likely be largely incurred at implementation of the policy. We showed that even significant implementation costs at the outset of a policy would not change the conclusion that these policies would be cost-effective or cost-saving. Increases in deceased donor organs could potentially affect donation rates from living donors. However, in our scenario analysis that modeled a reduction in living kidney donation, a policy that increased deceased organ donation remained cost-effective even with significant reductions in living donation.

Additionally, policies involving presumed consent or compensated donation raise important ethical issues that require consideration. For presumed consent, predominantly, the ethical issues center on weighing individual autonomy with social benefits and also balancing the risks of not procuring an organ when someone would have wanted it to be donated (under an opt-in system) versus the risk of procuring an organ when someone would not have wanted it to be donated (under an opt-out system).²⁰ For compensated donation, the concerns are that this policy may be coercive, particularly for lower income families.^{22,24,42} The societal benefit of increased organ donation is significant, however, and thus these ethical concerns must be weighed when considering implementation of a new policy.

This analysis does have important limitations that warrant attention. We did not model the impact that the policy would have on the transplantation rates of other

organs (e.g., liver, pancreas, heart, etc.). As most solid organ transplants have been shown to be cost-effective, consideration of all solid organ transplantation would likely result in even more cost-savings.^{26,43–45} The model also does not include all details associated with dialysis and organ transplantation, for example, the precise complexity associated with queuing and allocation of kidneys.

Although we do not simulate the specifics of organ allocation, others have looked at changing allocation mechanisms and have found them to be effective in improving outcomes. In addition, because we do not model the details of the waiting list, we assume that the increase in deceased donor transplantation rates will not cause waiting lists to drop to zero. Another study suggests a 25% increase in deceased donor transplants would not be sufficient to eliminate the kidney transplant waiting list.⁴⁶ However, if kidney donation increases were large enough to eliminate waiting lists, the gains in dollars and QALYs would not be as large as a linear prediction from our results would suggest. We refer readers to the work of Boxma et al.⁴⁷ to explore the impact of more dramatic increases in organ supply.

The impact of policy changes on deceased donor transplantation rates is uncertain. Studying changes in organ donation rates by examining historical experiences of countries implementing presumed consent policies may be subject to error and bias. Although the highest-quality between-country studies showed consistent findings, it may be possible that there were other unmeasured factors that also influenced organ donation rates that researchers were unable to account for. In the before-after studies, there could have been other uncontrolled factors that also concurrently influenced donation rates to change during the time period of policy changes. Although some of those factors were controlled for in the analyses, the potential for unmeasured factors exists, and thus could bias the impact of a presumed consent policy. Despite the limitations in these studies, it is notable that all these studies come to similar conclusions that presumed consent policies did increase deceased donor organ donation rates. However, a recent December 2015 opt-out law in Wales has not shown a discernable increase in organ donation rates.⁴⁸ Moreover, increases observed in other countries may not be completely applicable to the United States. The United States already has relatively high deceased organ donation rates in comparison to other countries, so there may be less relative improvement in donation rates seen when compared with the observed increases in organ donation rates in other international settings. In addition, a qualitative

study suggests that a host of other clinical and cultural factors may be as or more important in increasing donation rates.²¹ Finally, we lack estimates of the impact of payment policies on donation rates.

We did perform sensitivity analysis varying the increase in deceased donor organs to examine alternative potential levels of increase. Nonetheless, we were not able to examine other harder-to-quantify issues that may emerge if the increase in donors leads to lower-quality organs becoming available and being transplanted in higher-risk patients. This effect may lead to smaller gains than initially predicted.

We also determined a program that increased transplants by 5% could spend an additional \$7903 for every donor and still result in cost savings. Part of this additional spending could be used to address some of the limitations above.

In 1993, the United Network for Organ Sharing (UNOS) Presumed Consent Subcommittee evaluated the ethics of presumed consent and determined that at that time it was currently unadvisable.^{49,50} The most important objection at that time was that a 1985 Gallup survey showing only 7% support among the public.⁵¹ A more recent 2016 report created by the Organ Procurement and Transplantation Network (OPTN)/UNOS Ethics Committee also concluded that a presumed consent policy is not justified, mainly based on “deep-seated American cultural values.”⁵² However, this recent report does not cite the most recent (2012) National Survey of Organ Donation Attitudes and Behaviors, which reported that 51% of the US adult population supported or strongly supported a presumed consent policy.⁵³

Attitudes toward compensation vary. Studies suggest between 20%⁵⁴ and 59%⁵⁵ would be in favor of monetary or nonmonetary incentives for deceased donation. A 2017 randomized survey of 2666 Americans found 46% would favor compensating living donors, 21% would oppose it no matter what, and 18% would favor it if the policy increased supply significantly.⁵⁶



Conclusion

With possible changes in public attitudes toward presumed consent and compensated organ donation policies over the past 30 years, and given the potentially large gains in patient life years and health care dollars that our analysis and others^{3,4} show, it may be time to reopen a national conversation regarding the institution of these types of policies to increase deceased organ donation in the United States.

Authors' Note

A preliminary version of this research was presented at the 29th annual meeting of the Society for Medical Decision Making in 2020.

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Supplemental Material

Supplemental material for this article is available on the *Medical Decision Making Policy & Practice* website at <https://journals.sagepub.com/home/mpp>.

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