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ORIGINAL RESEARCH ARTICLE

Cost-Effectiveness and Budget Impact Analysis of Implementing a 'Soft Opt-Out' System for Kidney Donation in Australia

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Abstract

Introduction There is a severe shortage of donor organs globally. There is growing interest in understanding how a 'soft opt-out' organ donation system could help bridge the supply and demand gap for donor organs. This research aims to estimate the cost-effectiveness and budget impact of implementing a 'soft opt-out' organ donation system for kidney donation.

Methods A decision-analytic model was developed to estimate the incremental costs from a health system's perspective, quality-adjusted life-years (QALYs), and death averted of people who have kidney failure, comparing a 'soft opt-out' organ donation system to an 'opt-in' system. This study analysed three scenarios where the 'soft opt-out' system generated a 20%, 30%, and 40% increase in deceased organ donation rates over 20 years. A 5-year time horizon was adopted for the budget impact analysis.

Results A 20% increase in organ donation rates could have a cost saving of 650 million Australian dollars (A$) and a 10,400-QALY gain. A 20% increase would avert more than 1500 deaths, while a 40% increase would avert 3200 deaths over a time horizon of 20 years. Over the first 5 years, a 20% increase would have a net saving of A$53 million, increasing to A$106 million if the donation rate increases by 40%.

Conclusion A 'soft opt-out' organ donation system would return a cost saving for the healthcare system, a net gain in QALYs, and prevention of a significant number of deaths. Advantageous budgetary impact is important, but understanding the aversion for a 'soft opt-out' system in Australia is also important and remains a priority for further research.

Key Points for Decision Makers

Our modelling indicates that even a conservative 20% increase in organ donation rates in a 'soft opt-out' organ allocation system in Australia may result in a significant cost saving, a gain in quality-adjusted life-years (QALYs), and a significant number of lives being saved.

Evidence indicates that higher deceased donation rates may reduce living donation rates in comparison to current 'opt-in' systems. However, our sensitivity analysis found that a 'soft opt-out' system remains cost-effective until live donation rates are reduced by 50%. If the live donation rates are less than 50% of current rates, the 'soft opt-out' system becomes more costly and less effective.

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1 Introduction

Of the different kidney replacement therapies (i.e. dialysis and transplantation) for people with end-stage kidney disease, kidney transplantation delivers superior quality of life and survival [1, 2]. Furthermore, it is the most cost-effective kidney replacement modality [3, 4]. However, kidney donation worldwide does not currently meet transplant demand in most nations and is unlikely to meet future needs without significant reform. This is evident from 2017 data reporting that more than 100,000 patients are on United States waiting lists for kidney transplants [5], but only approximately 100,000 kidneys are transplanted globally each year [6].

A high refusal rate by families of potential deceased donors has led to a low donation rate to transplantation systems. The refusal rate in the UK [7] and Australia [8] is as high as 42%. Modelling different consent protocols has indicated that organ donation rates can shift significantly, depending on the protocol in practice [9, 10]. Organ donation beliefs and practices are often complex, with the Australian system an interesting case in point. Australia has one of the lowest kidney donation rates globally but high levels of community support for organ donation, with 80% willing to become organ donors [11]. The Australian transplantation system legislatively mandates ‘opt-in’ to organ donation, whereby potential donors must actively nominate to be a donor. Australians can record their consent or objection to donation on the Australian Organ Donation register. The Australian transplant community is advocating a shift in the country's transplantation system with ‘soft opt-out’ as one potential solution to bridge the gap between kidney organ supply and demand [12, 13].

‘Soft opt-out’ is an alternative approach to ‘opt-in’ organ donation, used in some regions of the world. This approach legislatively presumes that all potential donors are willing to donate unless explicitly registering their objection. The practice of approaching the next of kin to confirm the wishes of the deceased to donate their organs is preserved (i.e. next of kin retain veto power). Modelling of the ‘soft opt-out’ transplantation system indicates approximately 30% higher organ donation rates in comparison to ‘opt-in’ systems after accounting for potential confounding factors [14]. A real-world example of the impact of shifting to a ‘soft opt-out’ transplantation system is Wales. In 2015, Wales shifted to the ‘opt-out’ system, and consent rates increased significantly, although it is presently too early to accurately measure the sustained impact of this change [15, 16]. England and Scotland followed Wales in 2020 and 2021, respectively [17].

The implementation of alternative organ donation systems typically requires legislative changes. Unfortunately, governments typically have access to limited information when preparing legislation related to organ donation. Robust information related to the impact of potential legislative changes on likely population health impacts or healthcare budgets is typically scarce. The ethical, legal, and religious perspectives of individual rights, as exemplified by autonomy, and obligations as a community are often poorly contextualised to local jurisdictions. Important information is needed to conceptually frame the competing individual rights; this also includes the rights to life of those waiting for a kidney transplant (at high risk of mortality and morbidity), and the best use of finite healthcare resources.

There is urgency to generate robust evidence for informing legislation and policy regarding kidney donation systems due to the escalating health burden of chronic kidney disease as well as associated healthcare costs [18]. Kidney transplantation is the least costly of all effective kidney replacement strategies (i.e. dialysis and transplantation) [3, 4]. Cost-effective kidney replacement intervention is therefore directly dependent on the availability of kidneys for transplantation to suitable candidates. However, high-quality evidence regarding the likely impact of legislative changes related to alternative kidney donation systems and specifically the ‘soft opt-out’ approach to kidney donation remains scant.

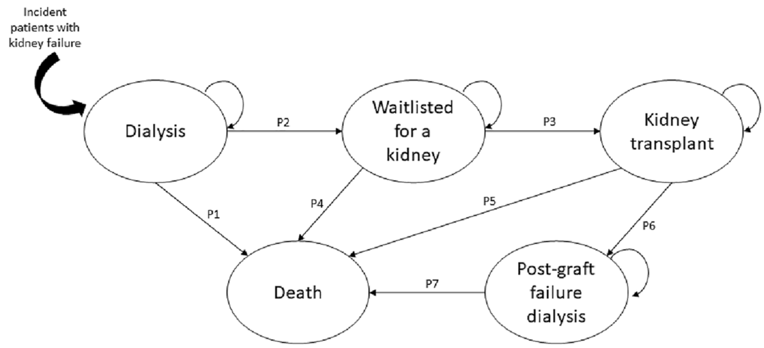
A ‘soft opt-out’ system would increase the transplantation rates of all organs and has the potential to save money and improve patient outcomes. This study aims to quantify, specifically, how a ‘soft opt-out’ kidney transplantation system impacts the mortality and quality-adjusted life-years (QALYs) of patients with kidney failure, and the financial impact on the healthcare system. We adopt cost-effectiveness and budget impact analysis approaches, methodologies suited to evaluating expected changes in a healthcare system that has implemented a new intervention [19]. This is the first international economic evaluation to evaluate the impact of implementing a national ‘soft opt-out’ system and is expected to provide essential information required for the public discourse on the potential introduction of a ‘soft opt-out’ transplantation system.

2 Methods

A decision-analytic model (Markov model) was developed using TreeAge Pro 2021 to estimate the incremental costs to the health system, QALYs, and death averted of people who have kidney failure, comparing a ‘soft opt-out’ organ donation system to the current 'opt-in' system (Fig. 1). The

target population was people with kidney failure undergoing dialysis and/or kidney transplantation (both live and deceased donor) in Australia.

Fig. 1 Markov model with the health states and possible transitions. *ESKD* end-stage kidney disease



Probability	Description
Incident patients with ESKD	Australian population x 0.0123%
P1	Annual probability of death while on dialysis (not waitlisted). Time-to-event analysis (Weibull regression) was used to calculate the time dependant transition probabilities. Data source: ANZDATA
P2	Annual probability of being waitlisted while on dialysis *P2 = Total annual transplants / Total population in kidney failure*
P3	Annual probability of being transplanted from all waitlisted patients. All transplants included both live and deceased donor kidney transplants *Deceased donor transplants = Australian population x Donation rate x Donation to transplant ratio* *Live donor transplants = Australian population x 0.0011%* *P3 = Total annual transplants / Total population waitlisted*
P4	Annual probability of death from all waitlisted patients. Data source: ANZDATA
P5	Annual probability of death after transplantation. Time-to-event analysis (Weibull regression) was used to calculate the time dependant transition probabilities. Data source: ANZDATA
P6	Annual probability of graft failure from all transplanted patients. Time-to-event analysis (Weibull regression) was used to calculate the time dependant transition probabilities. Data source: ANZDATA
P7	Annual probability of death from all graft failure patients. Data source: ANZDATA

2.1 Model Structure

The Markov model has five health states (Fig. 1): dialysis, waitlisted for a kidney, kidney transplant, dialysis after transplant failure, and death. The model starts with patients with kidney failure on dialysis ("dialysis" health state). In 2019, there were 13,931 people with kidney failure on dialysis in Australia; thus, it was assumed that in the beginning, there were 13,931 people in this health state [20]. Annually, new people (incident people) with kidney failure were added to the pool of people receiving dialysis. Between 2016 and 2019, the incidence of kidney failure requiring kidney replacement therapy ranged from 0.0116 to 0.0127% (average 0.0123%) of the total Australian population. Therefore, 0.0123% of the Australian population were added in each model cycle as incident people (supplementary Table S1, see the Electronic Supplementary Material). Australian population projections from 2020 to 2039 were sourced from the Australian Bureau of Statistics [21] and were used for each of the 20 cycles (20-year time horizon) in the model (see supplementary Table S1).

The "dialysis" health state tracked outcome scenarios such as death, waiting for a kidney, or remaining on dialysis. In the event of waitlisting, the model tracked subsequent outcome scenarios: death, kidney transplant, or remaining waitlisted. In Australia, 1100 people were on the waiting list for a kidney transplant in 2019 [22], and for the analysis, it was assumed that the waitlisted population increases proportionately to the Australian population (i.e. 0.005% of the Australian population). The total number of kidney transplants included both deceased donor and live donor transplants. The average number of live donor transplants has been 11 per 1,000,000 population for the last 10 years [22], and it was assumed that this rate remains constant throughout the time horizon. The number of deceased donor transplants per cycle was calculated (see Fig. 1 for the equation) using the Australian population, deceased donor organ donation rate (18 per million population [pmp] in 2020) and the donation to transplant ratio (1.52 in 2020). A recent systematic review reported four studies that have reviewed the change in deceased donor organ donation rates in opt-out' and 'opt-in' countries over 5–14 years [23]. These four studies reported that the 'soft opt-out' organ donation method increased the deceased donor organ donation rate within a range of 21–76%. The present study analysed three possible scenarios at the conservative end of this range of implementing the 'soft opt-out' system in Australia: 20%, 30%, and 40% increases in deceased donor organ donation rates. The annual probability of re-transplant in Australia is 1.6%, and this very low probability would not affect the model results. Therefore, it was assumed that once a graft fails, patients will not undergo another transplant; thus, the patient will either die or remain on dialysis.

The decision-analytic model was simulated for a 20-year time horizon, transitioning in 1-year cycles through the five health states described earlier. Effectiveness was evaluated using QALYs. Both costs and QALYs were discounted at an annual rate of 5%. The perspective of the analysis was from that of the healthcare payer.

2.2 Data Sources

Two Australian studies were used to source cost data for the model: “The economic impact of end-stage kidney disease in Australia—Projections to 2020" by Kidney Health Australia in 2010 [24] and "New South Wales Dialysis Costing Study” (2008) [25]. The first study reported the cost of a deceased donor kidney transplant in the first year as 81,549 Australian dollars (A$) (2010) and A$11,770 (2010) per year thereafter. The first-year cost included expenses related to surgery and hospitalisation, immunosuppressive therapy, specialist review and consultations, and other drugs, as well as donor costs for a transplant. Follow-up costs included expenses related to immunosuppressive treatment, drugs, and non-drug follow-up costs.

"New South Wales Dialysis Costing Study" reported the procedural (e.g. nursing, allied health, dialysis fluid and consumables, and depreciation costs) and nonprocedural costs (e.g. pharmacy, pathology, and medical expenses) related to different dialysis modalities. The final dialysis cost of A$69,089 was calculated as a blend of in-centre haemodialysis, satellite-centre haemodialysis, home haemodialysis, and peritoneal dialysis, in proportion to the usage patterns of the different dialysis modalities at the time. All costs were converted to 2021 Australian dollars for the current analysis using CCEMG—EPPI-Centre Cost Converter (https://eppi.ioe.ac.uk/costconversion/). The conversion is based on gross domestic product deflator index (‘GDPD values’) and purchasing power parities for GDP (‘PPP values’).

In the absence of Australian-sourced utility values for patients on dialysis or with a kidney transplant, we sourced utility values from a systematic review and a meta-analysis, which reviewed 190 studies reporting 326 utilities from over 56,000 people with chronic kidney disease [1] (Table 1). The majority of the selected studies (76%) were from the United States or Europe. Utilities had been derived from the EQ-5D utility instrument in 87% of the studies.

All transition probabilities were estimated from data sourced from the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) (Table 1) [26]. The information of people who started dialysis of any modality from

Table 1 Parameter estimates used in the model and sensitivity analysis

Parameter	Baseline estimate	Values for sensitivity analysis			Source
		Mean	SEM	Distribution	
Transition probabilities					
Death while on dialysis					
Lambda (λ)	0.1248	0.1248	0.0018	Weibull	ANZDATA
Gamma (ϒ)	1.0736	1.0736	0.0078		
Being waitlisted while on dialysis	Model generated parameter#				
Being transplanted from waitlisted patients	Model generated parameter$				
Death from all waitlisted patients	0.0184	0.0184	0.0036	Normal	ANZDATA
Death from all transplanted people					
Lambda (λ)	0.0240	0.0240	0.0013	Weibull	ANZDATA
Gamma (ϒ)	0.8693	0.8693	0.0259		
Graft failure from all transplanted patients					
Lambda (λ)	0.0419	0.0419	0.0018	Weibull	ANZDATA
Gamma (ϒ)	0.5315	0.5315	0.0171		
Death from all graft failure patients	0.1091	0.1091	0.0006	Normal	ANZDATA
Utility					
Transplant	0.82	0.82	0.0408	Beta	[1]
Dialysis	0.70	0.70	0.0408	Beta	[1]
Cost (in A$ 2021)					
Transplant (1st year)	105,965 (± 15%)			Uniform	[24]
Transplant (2nd year onwards)	14,751 (± 15%)			Uniform	[24]
Dialysis	86,590 (± 15%)			Uniform	[25]

A$ Australian dollars

#Total annual transplants divided by total population in kidney failure health state

$Total annual transplants divided by total population in waitlisted health state

January 1, 2011 to December 31, 2019 (n = 24,793) and the information of people who underwent a kidney transplant (live and deceased donors) for the first time from January 1, 2011 to December 31, 2019 were used to estimate the transition probabilities (n = 9806).

Seven transition probabilities were calculated from the datasets (Fig. 1).

Annual probability of:

1. Death while on dialysis (not waitlisted) (Fig. 1, P1)
2. Being waitlisted while on dialysis (Fig. 1, P2)
3. Being transplanted from all waitlisted patients (Fig. 1, P3)
4. Death from all waitlisted patients (Fig. 1, P4)
5. Death from all transplanted patients (Fig. 1, P5)
6. Graft failure from all transplanted patients (Fig. 1, P6)
7. Death from all graft failure patients (Fig. 1, P7)

Both time-dependent and fixed transition probabilities were used as transition probabilities. When time-dependent probabilities were used, the probabilities varied in each cycle and were dependent on how long the cohort had been modelled, while the same probability is used in every cycle when fixed-transition probabilities are used [27]. Four parametric distributions were employed to estimate the time-dependent transition probabilities: Weibull, Exponential, Log-logistic, and Log-normal. Weibull regression had the best visual and statistical fit (lowest Akaike and Bayesian information criterion [AIC, BIC] values [28]) and was therefore used in the final parameter estimation (supplementary Table S2, Electronic Supplementary Material). The Weibull distribution considers that the baseline hazard is time dependent and allows the baseline hazard to increase or decrease over time at different rates [29]. Lambda (λ) and Gamma (Υ) values derived from Weibull regression were used to estimate the time-dependent transition probabilities of annual probabilities of death while on dialysis (P1), death from all transplanted patients (P5), and graft failure from all transplanted patients (P6) (Table 1). Fixed transition probabilities were estimated for annual probability of death from all waitlisted patients (P4) and death from all graft failure patients (P7).

Annual probability of being waitlisted while on dialysis (P2) and annual probability of being transplanted from all waitlisted patients (P3) were dependent on the total number of transplants (deceased and live) performed in a cycle. They (P2 and P3) were expressed as a proportion of the total population in the “dialysis” health state and the “waitlisted for a kidney” health state, respectively.

2.3 Model Evaluation

The cohorts of people in different health states were simulated dynamically as they transitioned between health states over time. As people transitioned between different health states, they accumulated costs and utilities. The cost-effectiveness approach compared the accumulated costs and utilities between the 'opt-in' (usual care) and the 'soft opt-out' systems. The incremental cost-effectiveness ratio (ICER) was calculated using marginal QALY and costs. Each of the three scenarios—20%, 30%, and 40% increases in deceased donor organ donation rates if the 'soft opt-out' organ donation system is implemented—were modelled. The study used a conservative willingness to pay (WTP) value of A$28,000 per QALY gained, suggested by Edney et al., which reflects the opportunity cost of additional health system costs under a constrained budget [30].

2.4 Budget Impact Analysis

Budget impact analysis translates the results of the cost-effectiveness analyses to financial consequences relevant to decision-makers in health systems [31]. Current guidelines recommend that budget impact analysis should be conducted over relatively short time horizons, and costs and health outcomes should not necessarily be discounted [19]. Therefore, a 5-year time horizon was adopted for the budget impact analysis, and the costs and QALY were not discounted. The total expenditure of the two options (‘opt-in’ vs ‘soft opt-out’) was aggregated over this time horizon. The difference between these two cost estimates indicates the amount of cost savings if the kidney transplantation system shifts to a 'soft opt-out' in Australia. It did not include the financial benefit to other organ transplant systems (e.g. liver, lungs, heart), which were considered outside the scope of the present study. A separate analysis was done for each of the three scenarios in comparison to the current ‘opt-in’ system.

2.5 Sensitivity Analysis

Higher deceased donation rates may reduce living donation rates in comparison to current ‘opt-in’ systems (Arshad et al. [32]). Therefore, we conducted a sensitivity analysis to examine whether findings were robust against assumptions related to living donation rates. We lowered rates of living donation in our modelling to find the threshold rate below which a 'soft opt-out' system was no longer considered to be cost-effective (less effective or ICER more than the WTP value).

We explored the uncertainty in the parameters used in the model, and the effect on the cost-effectiveness results, using probabilistic sensitivity analysis (PSA). Specifically, Monte Carlo simulations were performed on 10,000 iterations [33]. The input parameters were deemed to be distributed probabilistically to account for the full range of potential parameter uncertainty (Table 1). Incremental net monetary benefit (INMB) was used to summarise uncertainty in the cost-effectiveness results. INMB is the incremental difference between the economic value of health benefits and the change in costs between the two options.

3 Results

Base-case analysis found the 'soft opt-out' system was the dominant option compared to the 'opt-in' system (i.e. both cost saving and more effective, Table 2). This was true for each of the three scenarios considered: 20%, 30%, and 40% increases in deceased donor organ donation rates. Over a 20-year time horizon, a 20% increment in transplantations was associated with a saving of A$508 million, while a 40% increment would likely save A$1.016 billion. The incremental effectiveness (effectiveness of the 'soft opt-out' system minus the 'opt-in' system) of a 20% increment in donation rate was estimated at 12,217 QALYs. This increased to 24,433 QALYs if implementing the 'soft opt-out' system was associated with a 40% higher donation rate. The number of deaths averted by a 'soft opt-out' system is displayed in supplementary Figure S1 (see the Electronic Supplementary Material). A 20% increment in donation rate was estimated to prevent 1574 deaths, while a 40% increment would avert 3148 deaths over a 20-year time horizon.

The results of the budget impact analyses are presented in Table 3. The time horizon for this analysis was 5 years. A 20% increment in donation rate would save dialysis-related costs nearly A$150 million. In contrast, transplant-related costs would increase by almost A$100 million, with a net saving of A$53 million. The net savings would increase to A$106 million if the donation rate increases to 40%. Over a 10-year time horizon, the transplant-related annual costs gradually increase with time, while the dialysis-related cost savings gradually plateau (Fig. 2). A similar plateauing is seen in the yearly total cost saving as well.

Scenario analyses found that a 'soft opt-out' system remains cost-effective until live donation rates are reduced by 50%. If the live donation rates are less than 50% of current rates, the 'soft opt-out' system becomes more costly and less effective. PSAs resulted in cost savings (negative incremental cost), greater effectiveness (positive incremental QALY), and highest net monetary benefit (positive INMB) in a ‘soft opt-out’ system in all of the iterations (Fig. 3). This means a 'soft opt-out' system's probability of not being cost-effective is very low (less than 0.001). The expected maximum and minimum cost saving, QALY gain, and net monetary benefit were estimated from the 10,000 iterations of the PSAs. A 20% increment in donation rate could have a maximum cost saving of A$950 million (minimum A$310 million), a

Table 2 Cost-effectiveness results related to renal care after implementing a 'soft opt-out' organ donation system: base case for 20-year time horizon

Scenario	Donation method	Cost (2021 A$ in millions)	Incremental cost (2021 A$ in millions)	Effectiveness	Incremental effectiveness	ICER
20% increment	Soft opt-out	37,559	−508	434,375	12,217	Dominant
	Opt-in	38,066		422,158		
30% increment	Soft opt-out	37,305	−762	440,483	18,325	Dominant
	Opt-in	38,066		422,158		
40% increment	Soft opt-out	37,051	−1016	446,591	24,433	Dominant
	Opt-in	38,066		422,158		

A$ Australian dollars, *ICER* incremental cost-effectiveness ratio

Table 3 Budget impact analysis results related to renal care after implementing a 'soft opt-out' organ donation system: 5-year time horizon

Scenario	Cost saving: total cost (2021 A$ in millions)#	Cost saving: transplant cost (2021 A$ in millions)$	Cost saving: dialysis cost (2021 A$ in millions)##
20% increment	53.0	−95.3	148.2
30% increment	79.5	−142.9	222.4
40% increment	106.0	−190.5	296.5

A$ Australian dollars

#Incremental total cost = total cost of 'opt-in' system − total cost of ‘soft opt-out’ system

$Incremental transplant cost = transplant cost of 'opt-in' system − transplant cost of 'soft opt-out' system

##Incremental dialysis cost = dialysis cost of 'opt-in' system − dialysis cost of 'soft opt-in' system

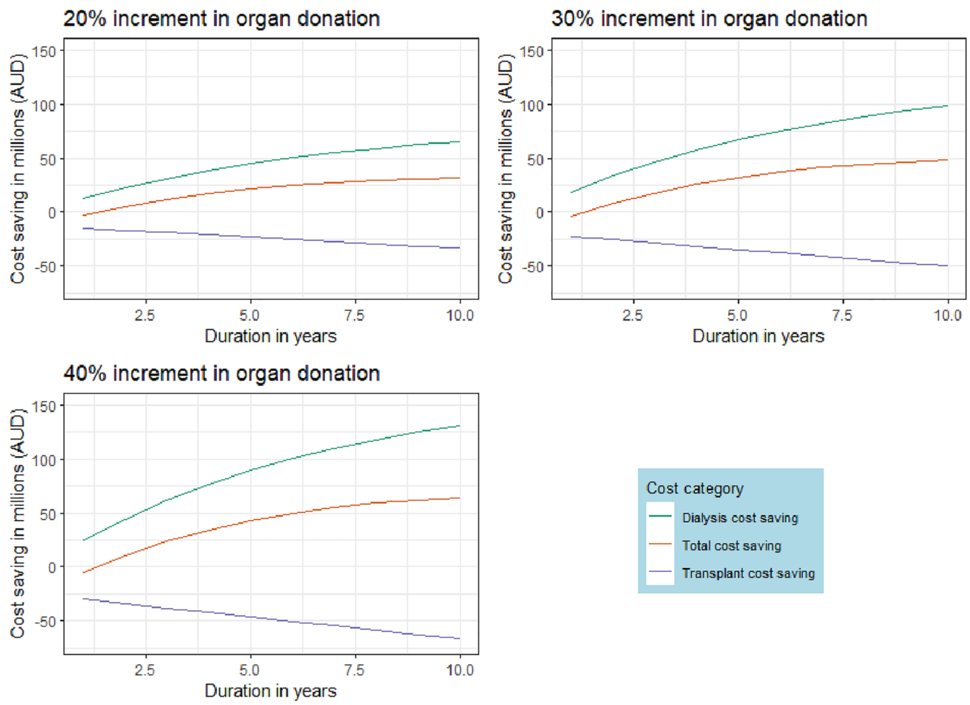
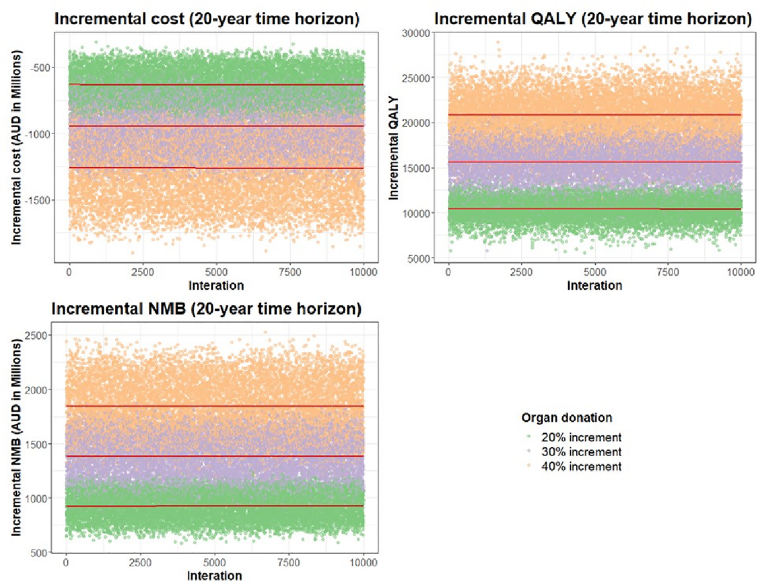


Fig. 2 Different cost-saving categories (total, transplant, and dialysis) according to three different organ increment scenarios. *AUD* Australian dollars



		Incremental cost (2021 A$ in millions)	Incremental QALY	Incremental NMB (2021 A$ in millions)
20% increase	Mean	-632.4	10,409	923.9
	Minimum	-949.1	5,589	585.8
	Maximum	-312.6	14,149	1,282.5
30% increase	Mean	-946.0	15,598	1,382.8
	Minimum	-1,406.6	5,758.7	860.8
	Maximum	-479.8	21,529.4	1,876.9
40% increase	Mean	-1,261.9	20,794.4	1,844.2
	Minimum	-1,898.1	11,396.5	1,161.2
	Maximum	-666.6	28,878.7	2,526.5

Fig. 3 Incremental cost, QALY and NMB for 'soft opt-out' organ donation system compared to the current ('opt-in') system. Each *dot* in all three graphs indicates the values generated from the 10,000 iterations in PSA. Negative incremental cost indicates a cost saving compared to current practice. Positive incremental QALY indicates more effectiveness compared to the current practice. Positive incremental NMB indicates the 'soft opt-out' system is cost-effective compared to current practice. *A$/AUD* Australian dollars, *NMB* net monetary benefit, *PSA* probabilistic sensitivity analysis, *QALY* quality-adjusted life-year

14,150-QALY gain (minimum 5589), and a A$1.3 billion gain (minimum A$590 million) in net monetary benefit over the 20-year time horizon. Similarly, a 40% increment in donation rate could have a maximum cost saving of A$1.9 billion (minimum A$670 million), a 28,900-QALY gain (minimum 11,400), and a A$2.5 billion gain (minimum A$1.2 billion) in net monetary benefit.

4 Discussion

There is a severe shortage of donor organs globally, resulting in an increasing number of people waiting for a transplant. A 'soft opt-out' organ allocation system is one potential strategy to expand the pool of donor organs. This strategy has produced promising results in several countries where it has been implemented. The current study is the first evaluation to assess the cost-effectiveness and downstream budgetary impact of implementing a 'soft opt-out' organ allocation system. Our modelling indicates that even a conservative 20% increment in organ donation rate in a 'soft opt-out' organ allocation system in Australia may result in a significant cost saving, a gain in QALYs, and a significant number of lives being saved.

It is important to note that this model was representative of the Australian population, where organ transplant success rate is among the best in the world [34]. While it is likely that similar patterns of benefit would be observed in other national cohorts with high rates of transplantation success, the magnitude of those benefits may be dependent on organ donation rates under their current organ donation systems. Australia's deceased organ donation rate at 18 pmp in 2019 is lower than some other high-income countries, including the United States (30.7 pmp), Spain (43.6 pmp), France (28.6 pmp), Portugal (32.6 pmp), and Finland (24.6 pmp) [32]. Although it is likely that the impact of ‘soft opt-out’ systems on costs, QALYs, and deaths averted will be favourable in these other high-income countries, the magnitude of those benefits may not be equivalent to those modelled for the Australian population.

It has been estimated that only 2% of people who die in hospitals fulfil the criteria for an organ donor [8, 35]. The causes of death for those eligible to donate organs typically include either cerebral hypoxia/ischaemia or intracranial haemorrhage or traumatic brain injury, primarily due to either road traffic accidents or strokes [36]. Of important consequence for people requiring organ transplantation is that death due to strokes and road trauma are decreasing among industrialised countries due to excellent clinical, public health, and road safety interventions. For example, in the national context of the present study, the rate of road trauma-related fatalities in Australia has reduced by approximately 25% over the last decade [37], and fatalities related to stroke have dropped by 75% over the last 2 decades and are expected to drop further [38]. While these reductions in fatality rates are to be lauded, the ongoing success of public health and safety initiatives related to stroke and road trauma does heighten the need for alternative approaches to optimising rates of successful transplantation.

Several countries have set the precedent of implementing a 'soft opt-out' organ donation system with the intent to increase organ donation rates. Wales (2015), Ireland (2019), England (2020), and Scotland (2021) all implemented this system recently. The system presumes that every donor is willing to donate unless they have specifically registered their objection. However, a 'soft opt-out' system has the added characteristic that family wishes are always consulted and they have the power of veto. Our study assumed that, if the 'soft opt-out' system is implemented, the donation rate will increase at least by 20%. This assumption was based on the lower estimates arising from global literature and may be considered conservative.

A recent systematic review compared the impact of implementing presumed consent organ donation systems in six countries (Argentina, Chile, Finland, Poland, Slovakia, and Uruguay) using retrospective data [39]. These countries were selected on the basis that they had post-implementation data for at least 3 years and a total population of more than 2 million. All countries demonstrated a statistically significant increase in liver transplantation and a statistically significant increase in kidney transplantation in Argentina, Poland, Slovakia, and Uruguay. Pooled analysis of all the countries comparing more than 40 years of pre- and post-implementation data showed a 48% increase in kidney transplants and a 100% increase in liver transplants. The study performed a matched control analysis to determine if countries with ‘opt-in’ systems (Ireland, Israel, Germany, and Romania) experienced a similar rise in organ donation rates during the selected period. Except for Romania, none of the countries showed a statistically significant increase in the transplantation rates. Another review reported four studies that have tracked the change in deceased donor organ donation rates of the ‘opt-out’ and ‘opt-in’ countries over 5–14 years [23]. Over the study periods, deceased donor organ donation rates increased within a range of 21–76% in countries with an ‘opt-out’ organ donation system.

However, Arshad et al. compared the donation and transplant rates of 17 countries with ‘opt-out’ systems and 18 countries with ‘opt-in’ systems. The study found no statistically significant difference in the donation rates between the two groups [32]. This highlights the importance of context. Culture, including health systems and people's behaviour, differs across countries. For this reason, intra-country comparisons (pre- and post-implementation) are likely to provide the most robust evidence of the effect on donation rates of changing the donor organ system.

We factored in the possibility that live donor rates may decline in a transplantation system that moves to ‘opt-out’ [32]. Live donor transplants account for only 18% of the transplants in Australia. Our modelling demonstrated that an 'opt-out' system would continue to be cost-effective even with reductions of up to 50% in the living donation rates (9% of all transplants).

Consenting to donate organs is a very personal action. It has been reported that people living in countries with ‘soft opt-out’ systems have a tendency to take a societal perspective that organ donation is the morally right thing to do [40]. Our study demonstrated positive societal impacts of a 'soft opt-out' system with improved survival and better quality of life for people with kidney failure. Benefits of greater availability of organs for transplantation may extend further to broader society that were beyond the scope of the present study. Moreover, benefits are likely amplified when other organs in addition to the kidney are transplanted in a single consent procedure, which was also beyond the scope of the present study.

The current study has several limitations. Firstly, all the transition probabilities used in the two organ donation systems were derived from a retrospective data set. Past data may not be repeated into the future, mainly when practice changes, e.g. implementation of a 'soft opt-out' system. Specifically, practice characteristics such as organ acceptance behaviour and availability of donor kidneys are examples of change that are likely to impact transplant and patient survival post-implementation of a 'soft opt-out' system. Modelling of this level of detail, and other possible parameters in a changed transplant system, is beyond the scope of this study. The authors believe the current study is done with the best currently available information. Secondly, we assumed that those who are waitlisted would either remain waitlisted, be transplanted, or die. However, some waitlisted patients can be taken off the list temporarily or indefinitely, primarily due to other competing health events. This has not been modelled in the analyses. Thirdly, typically in PSA, the cost parameters would be considered to have a gamma distribution. However, we could only fit a uniform distribution due to limitations in the data source. Uniform distributions for transplant costs have been used before [41], and evidence indicates that the transplant and dialysis costs are not expected to be skewed [27]. Therefore, the authors believe that this limitation would not affect the results.

5 Conclusion

In conclusion, after implementing a 'soft opt-out' organ allocation system, an increase in the organ donation rate as small as 20% may result in significant cost savings, a gain in QALYs, and a significant number of human lives being saved. However, the willingness to accept a ‘soft opt-out’ system is understudied in most national contexts, including in the Australian context on which this study was based.

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Declarations

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Ethics approval This study has been granted ethics approval by the Queensland University of Technology Human Research Ethics Committee (No:4030). All patients consented to be enrolled in the ANZDATA registry, and the need to consent for this study was waived. Administrative permission to access data was provided by the ANZDATA registry.

Consent to participate Not applicable.

Consent for publication (from patients/participants) Not applicable.

Availability of data and material The datasets generated and/or analysed during the current study are available from the corresponding author on request.

Code availability The code that supports the findings of this study is available from the corresponding author on request.

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