

Comparison of organ donation and transplantation rates between opt-out and opt-in systems



see commentary on page 1301

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Studies comparing opt-out and opt-in approaches to organ donation have generally suggested higher donation and transplantation rates in countries with an opt-out strategy. We compared organ donation and transplantation rates between countries with opt-out versus opt-in systems to investigate possible differences in the contemporary era. Data were analysed for 35 countries registered with the Organisation for Economic Co-operation and Development (17 countries classified as opt-out, 18 classified as opt-in) and obtained organ donation and transplantation rates for 2016 from the Global Observatory for Donation and Transplantation. Compared to opt-in countries, opt-out countries had fewer living donors per million population (4.8 versus 15.7, respectively) with no significant difference in deceased donors (20.3 versus 15.4, respectively). Overall, no significant difference was observed in rates of kidney (35.2 versus 42.3 respectively), non-renal (28.7 versus 20.9, respectively), or total solid organ transplantation (63.6 versus 61.7, respectively). In a multivariate linear regression model, an opt-out system was independently predictive of fewer living donors but was not associated with the number of deceased donors or with transplantation rates. Apart from the observed difference in the rates of living donation, our data demonstrate no significant difference in deceased donation or solid organ transplantation activity between opt-out versus opt-in countries. This suggests that other barriers to organ donation must be addressed, even in settings where consent for donation is presumed.

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There is a continued disparity between the supply and demand for organs across countries with an established infrastructure to facilitate transplantation. This has led to development of different strategies to bridge this gap to ensure people do not die waiting for organ transplantation. One of the most topical discussions in global organ procurement is the relative merits of an opt-out system for organ donation (termed “presumed or deemed consent”) versus the opt-in system (termed “explicit consent”) to increase organ donor rates, with both pro and con positions keenly

Editor’s Note

Increasing organ donation worldwide by adopting an “opt-out” or presumed consent model for organ donation is a hot and popular topic in the popular press and an issue for legislators, politicians, and law makers. In this issue of *Kidney International*, organ donation and transplantation rates in 35 similar countries registered with the Organization for Economic Co-operation and Development (OECD) who had either “opt-in” or “opt-out” (presumed consent) systems are presented. The major findings compared opt-out to opt-in countries; there was no significant difference in total deceased-donor rates in per million populations but there was a reduction in living donor numbers in the opt-out countries. These novel findings suggest that a simplistic switch to the “opt-out” model has unintended consequences for living organ donation that does not provide a “quick fix” to improve donor rates that has been previously suggested. The authors conclude that greater emphasis on education and informing the general population about the benefits of transplantation is the preferred way to achieve an increase in organ donation. These findings have important implications for transplant clinicians and health policymakers when considering the merits of organ donation strategies.

debated.^{1,2} The psychological rationale to support opt-out systems is that choosing organ donation consent as the default option bridges the gap between intention and action,³ facilitating more organ donor registrants as a consequence. Apart from bypassing the possible apathy or protracted procrastinations of people who have every good intention to donate, choosing opt-out as the default mechanism for organ donation also notifies individuals of the recommended course of action from policymakers. For example, experimental evidence suggests presuming organ donation is the default option for citizens may make them consider that to be the natural choice, whereas presuming the opposite makes the choice special rather than the norm.⁴

This issue has now become an important political matter for policymakers, with many countries that have explicit consent contemplating (or planning) conversion to presumed consent in efforts to boost organ donation rates. For example, the UK Parliament has committed the government to introducing presumed consent in England after a brief

consultation process⁵ and is likely to be implemented by 2020. The underlying justification for such change relies on published evidence that suggests improved donation rates, and subsequent increase in transplantation activity, among countries with opt-out systems. For example, the analysis from Shepherd and colleagues⁶ demonstrated opt-out countries have higher rates of kidney and liver transplantation activity from more deceased organ donors (despite lower rates of living donors). Furthermore, Abadie and Gay⁷ identified a “positive and sizable effect” of presumed consent legislation on organ donor rates independent of other factors in a cross-country panel study. However, other analyses have derived more ambivalent conclusions regarding the benefits of opt-out versus opt-in once we factor in other considerations. For example, Coppen and colleagues⁸ found no difference in organ donation rates between opt-out versus opt-in countries once mortality rates were factored into the analysis. Rithalia and colleagues⁹ found ambivalent evidence from their analysis to suggest presumed consent alone was responsible

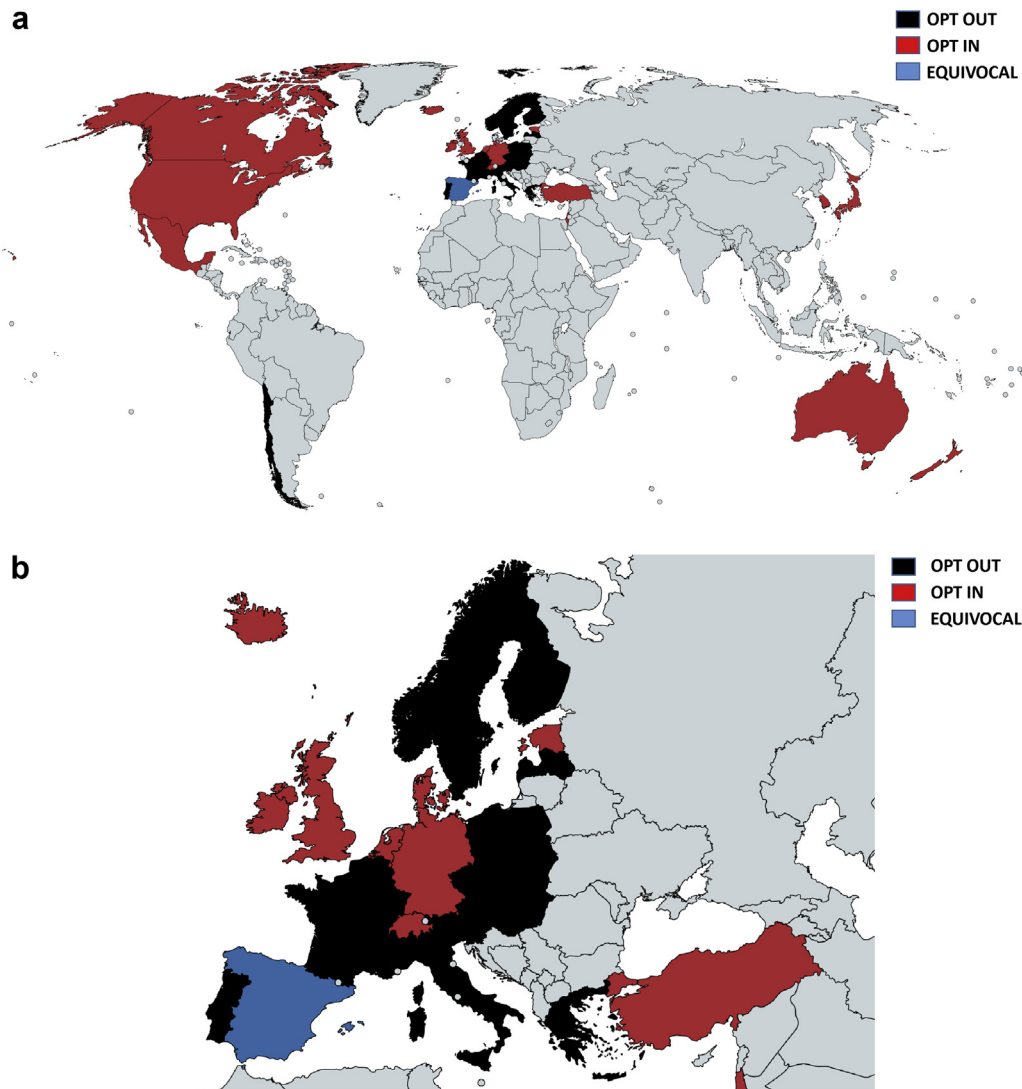


Figure 1 | Map of opt-out versus opt-in countries from both (a) a global and (b) European perspective.

Table 1 | Snapshot of OECD countries used in the analysis with donation rates and transplantation activity (per million population)

Country	System	Deceased donation rates	Living donation rates	Total transplant activity
Australia	In	20.6	10.9	72.6
Austria	Out	24.8	7.9	89.3
Belgium	Out	30.7	9.6	90.0
Canada	In	20.0	14.9	79.6
Chile ^a	Out	7.4	5.3	24.5
Czech Republic	Out	25.1	4.4	75.4
Denmark	In	17.4	19.0	67.5
Estonia	In	16.8	3.1	43.5
Finland	Out	24.6	4.0	72.2
France	Out	28.6	8.9	90.8
Germany	In	10.4	7.9	45.0
Greece	Out	4.6	4.4	13.5
Hungary	Out	18.7	3.5	51.8
Iceland	In	26.9	14.9	14.9
Ireland ^b	In	16.2	10.5	58.8
Israel ^c	In	10.2	27.6	62.5
Italy	Out	24.9	4.8	63.6
Japan	In	0.8	14.6	29.9
Korea	In	11.4	42.4	79.3
Latvia	Out	15.4	5.1	31.8
Luxembourg	Out	5.1	n/a	n/a
Mexico	In	3.6	16.4	24.7
Netherlands ^d	In	14.7	33.9	75.4
New Zealand	In	13.0	18.1	55.7
Norway	Out	20.9	8.9	78.2
Poland	Out	14.2	2.0	42.6
Portugal	Out	32.6	6.3	82.2
Slovak Republic	Out	13.2	3.5	36.7
Slovenia	Out	20.2	1.0	52.4
Spain	Out/in ^e	43.6	8.0	103.9
Sweden	Out	20.3	14.4	80.8
Switzerland	In	13.1	15.5	60.4
Turkey	In	7.0	45.1	60.9
United Kingdom ^f	In	21.2	15.9	73.7
United States	In	30.7	18.4	106.1

^aOpt-out and reciprocity.^bPlanning move to opt-out.^cReciprocity system.^dPlanning move to opt-out.^eCan be considered both opt-in and opt-out. Included as opt-in for this analysis.^fWales introduced opt-out December 1, 2015, whereas the rest of the United Kingdom remains opt-in at present.

for any variation of organ donation rates between countries. Therefore, a summary review of the empirical evidence from published literature is difficult because studies use heterogeneous methodology, subject countries, and analytical techniques. Another criticism is that published studies in the literature are now dated and do not reflect contemporary organ donation and transplantation activity.

Obtaining a contemporary snapshot of organ donation–transplantation rates between opt-out versus opt-in countries, adjusted for country-specific socioeconomic factors that could confound organ donation–transplantation activity rates, would aid our decision-making regarding the relative

Table 2 | Comparison of opt-out versus opt-in countries

Variable	Opt-out	Opt-in	P
Population, in millions	9.7 (5.4–14.7)	30.54 (5.5–81.1)	0.143
European country, %	94.1	50.0	0.005
Length of time of transplant policy	21.0 (10.0–27.5)	18.0 (13.0–36.0)	0.602
Gross domestic product (GDP) at purchasing power parity, Int\$	324.0 (187.7–490.5)	409.0 (65.8–2049.8)	0.551
Household debt, % of net disposable income	104.3 (66.8–162.9)	122.0 (74.9–194.4)	0.533
Government debt, % of GDP	72.2 (39.2–95.1)	78.3 (43.8–116.1)	0.621
Tax, % of personal income	9.2 (5.3–12.7)	8.7 (4.6–14.2)	0.961
Road traffic accidents, fatalities per 100,000 inhabitants	455 (232–921)	360 (160–2691)	0.998
Legal system			
Common law	0 (0.0)	7 (38.9)	0.005
Civil law	17 (100.0)	11 (61.1)	
Main religion			
Christianity	16 (94.1)	13 (76.5)	0.315
Islam	0 (0.0)	0 (0.0)	
Judaism	0 (0.0)	1 (5.9)	
Irreligious	1 (5.9)	3 (17.6)	
Hospital beds, per 1000 inhabitants	5.0 (3.2–6.6)	3.1 (2.6–4.6)	0.051
Health spending, % of GDP	8.1 (7.4–10.8)	9.2 (7.7–10.9)	0.613
Tertiary education, % achieving	32.8 (20.8–41.1)	41.5 (22.2–47.8)	0.365

Values are median (interquartile range), with *P* values from Mann-Whitney U tests, or *n* (%), with *P* values from χ^2 tests, as applicable. Bold values are significant at *P* < 0.05.

merit of one organ donation system over the other. Therefore, the aim of this study was to undertake a cross-sectional study of developed countries to compare organ donations rates and corresponding solid organ transplantation activity to determine if they differ between countries with opt-out versus opt-in systems.

RESULTS

Opt-out versus opt-in country stratification

Of our 35 Organisation for Economic Co-operation and Development (OECD)-registered countries, 17 are classified as opt-out (or presumed consent) countries, based on the definitions stated in Methods (below), and 18 classed as opt-in countries (Figure 1, Table 1). In [Supplementary Table S1](#) we provide a more detailed breakdown of each country included in the analysis with specific links to organ donation legislation.

Differences between opt-out versus opt-in country profiles

Opt-out countries exclusively practiced civil law systems compared with opt-in countries (100.0% vs. 61.1%, respectively; *P* = 0.005), with 38.9% of opt-in countries having a common law system. Furthermore, opt-out countries were more likely to be European (94.1% vs. 50.0%, respectively; *P* = 0.005). There was no statistically significant difference

Table 3 | Comparison of organ donation rates and solid organ transplantation activity between opt-out versus opt-in countries (latest year)

Variable	Opt-out	Opt-in	P
<i>Organ donation rates (per million population)</i>			
Total deceased donors	20.3 (13.7–25.0)	15.4 (10.4–20.7)	0.195
Total living donors	4.8 (3.5–8.4)	15.7 (10.8–21.2)	<0.001
<i>Organ-specific transplantation activity (per million population)</i>			
Deceased kidney transplantation	30.3 (22.0–40.7)	23.4 (14.1–33.8)	0.134
Living kidney transplantation	4.5 (3.5–7.0)	15.2 (10.8–20.1)	<0.001
Deceased liver transplantation	13.0 (5.6–20.3)	10.2 (6.9–13.0)	0.483
Living liver transplantation	0.0 (0.0–0.2)	0.6 (0.0–1.5)	0.025
Heart transplantation	4.5 (2.1–6.6)	3.1 (0.7–5.1)	0.083
Lung transplantation	2.5 (0.0–6.2)	4.1 (1.4–6.8)	0.219
Pancreas transplantation	1.1 (0.1–2.7)	1.4 (0.2–1.7)	0.961
Small bowel transplantation	0.0 (0.0–0.0)	0.0 (0.0–0.1)	0.309
<i>Overall solid organ transplantation activity (per million population)</i>			
Overall kidney transplantation	35.2 (24.2–46.5)	42.3 (30.4–48.0)	0.405
Overall nonrenal transplantation	28.7 (9.1–34.5)	20.9 (17.5–27.3)	0.606
Overall solid organ transplantation	63.6 (34.3–81.5)	61.7 (44.6–76.4)	0.909

Values are median (interquartile range), with P values from Mann-Whitney U tests. Bold values are significant at $P < 0.05$.

between opt-out versus opt-in countries in the following social and economic variables: population, gross domestic product, road traffic accidents, religious affiliation, percentage achieving tertiary education, hospital beds, household debt, government debt, tax on personal income, or health spending (Table 2).

Organ donation rates (all figures per million population)

Comparing opt-out with opt-in countries we observed no significant difference in total deceased donor rates (20.3 vs. 15.4, respectively; $P = 0.195$), but there were significantly less living donors (4.8 vs. 15.7, respectively; $P < 0.001$) among opt-out countries (Table 3).

Organ-specific solid organ transplantation activity (all figures per million population)

Table 3 also highlights the different rates of transplantation activity differentiated into different solid organs. Although numerically opt-out versus opt-in countries appeared to have more deceased donor kidney transplants, this was not found to be statistically significant (30.3 vs. 23.4, respectively; $P = 0.134$). However, we did observe significantly less living donor kidney transplants among opt-out versus opt-in countries (4.5 vs. 15.2, respectively; $P < 0.001$). Altogether, there was no difference in overall kidney transplantation rates between opt-out versus opt-in countries (35.2 vs. 42.3, respectively; $P = 0.405$).

There was no significant difference in overall rates of liver transplantation between opt-out versus opt-in countries. However, although no significant differences were found in deceased donor liver transplantations (13.0 vs. 10.2, respectively; $P = 0.483$), opt-out countries had a significantly lower rate of living donor liver transplantation (0.0 vs. 0.6, respectively; $P = 0.025$). No significant differences were observed with other solid organ transplants, including heart, lung, pancreas, or small bowel. We observed no significant

difference in total transplantation rates between opt-out versus opt-in countries when overall nonrenal (28.7 vs. 20.9, respectively; $P = 0.606$) or overall solid organ transplantation activity was analyzed (63.6 vs. 61.7, respectively; $P = 0.909$).

We repeated the analysis by exploring 5 years of cumulative data relating to organ donation and transplantation activity (2012–2016). The results were similar to the analysis above, with no significant difference between opt-out versus opt-in countries in either kidney transplant rates (36.3 vs. 35.8, respectively; $P = 0.792$), nonrenal transplant rates (21.4 vs. 20.7, respectively; $P = 0.712$), or total transplantation rates (57.5 vs. 57.1, respectively; $P = 0.915$). No significant difference was identified when each individual year from 2012 to 2016 was separately analyzed. Furthermore, we repeated the analysis and calculated the rate of transplantation per 10,000 deaths to see whether death rates influence transplantation. No significant difference was identified in the deceased donor transplant rates of all solid organs when analyzed this way.

Multivariate analysis

In a multivariate linear regression model, adjusted for country-specific variables, having an opt-out organ donation system was not independently predictive of deceased donor kidney transplantation rates ($\beta = -0.560$ [95% confidence interval {CI}, -7.58 to $+6.466$], $P = 0.872$) but was predictive of decreased living organ donor rates ($\beta = -9.97$ [95% CI, -16.50 to -3.49], $P = 0.004$). No significant difference was observed in overall kidney, nonrenal, or total solid organ transplantation activity stratified by whether countries had an opt-out or opt-in organ donation system.

Sensitivity analysis (all figures per million population)

Because Spain has been frequently analyzed as an opt-out country, we repeated our analysis with Spain reclassified as opt-out (Table 4). In this sensitivity analysis, when comparing

Table 4 | Sensitivity analysis with Spain regarded as an opt-out country

Variable	Opt-out	Opt-in	P
<i>Organ donation rates (per million population)</i>			
Total deceased donors	20.6 (14.0–25.9)	14.7 (10.3–20.3)	0.062
Total living donors	5.0 (3.5–8.2)	15.9 (12.8–23.3)	<0.001
<i>Organ-specific transplantation activity (per million population)</i>			
Deceased kidney transplantation	31.0 (22.4–41.8)	21.8 (12.7–31.3)	0.038
Living kidney transplantation	4.6 (3.5–7.5)	15.4 (11.2–21.2)	<0.001
Deceased liver transplantation	14.9 (6.2–20.5)	10.1 (6.2–12.5)	0.219
Living liver transplantation	0.0 (0.0–0.3)	0.6 (0.0–1.6)	0.035
Heart transplantation	5.0 (2.4–6.6)	3.1 (0.6–4.9)	0.038
Lung transplantation	2.5 (0.0–6.4)	3.9 (1.1–6.6)	0.386
Pancreas transplantation	1.3 (0.2–2.6)	1.3 (0.2–1.8)	0.807
Small bowel transplantation	0.0 (0.0–0.1)	0.0 (0.0–0.1)	0.630
<i>Overall solid organ transplantation activity (per million population)</i>			
Overall kidney transplantation	39.2 (25.2–47.7)	42.3 (28.8–46.6)	0.782
Overall nonrenal transplantation	29.5 (9.7–35.5)	20.2 (17.2–24.4)	0.325
Overall solid organ transplantation	67.9 (35.5–84.0)	60.0 (44.3–74.5)	0.708

Values are median (interquartile range), with P values from Mann-Whitney U tests. Bold values are significant at $P < 0.05$.

18 opt-out (including Spain) versus 17 opt-in (excluding Spain) countries, we observed no significant difference in deceased organ donors among opt-out versus opt-in countries (20.6 vs. 14.7, respectively; $P = 0.062$) but did observe a significant drop in living organ donor rates (5.0 vs. 15.9, respectively; $P < 0.001$). From a kidney transplantation perspective, comparing opt-out versus opt-in countries we observed more deceased donor kidney transplants (31.0 vs. 21.8, respectively; $P = 0.038$), less living donor kidney transplants (4.6 vs. 15.4, respectively; $P < 0.001$), but similar overall kidney transplantation activity (39.2 vs. 42.3, respectively; $P = 0.782$). There was no significant difference in nonrenal transplantation activity (29.5 vs. 20.2, respectively; $P = 0.325$) or overall solid organ transplantation activity (67.9 vs. 60.0, respectively; $P = 0.708$).

Repeating the multivariate linear regression model showed no significant influence of an opt-out policy on deceased organ donation ($\beta = 6.71$ [95% CI, -0.47 to $+13.86$], $P = 0.070$) but did show a significant reduction in living organ donation ($\beta = -12.51$ [95% CI, -18.51 to -6.51], $P < 0.001$). There was no effect on overall transplantation rates.

DISCUSSION

In our up-to-date analysis of organ donation rates and solid organ transplantation activity comparing opt-out with opt-in countries, other than reduced living donor rates among opt-out countries, we observed no overall difference in kidney transplantation rates, nonrenal transplantation rates, or total solid organ transplantation activity. Our analysis suggests there may be a difference in organ donation type patterns between opt-out versus opt-in countries, but overall transplantation rates did not differ. This has implications for countries considering the introduction of presumed consent and strategies to boost living donation rates.

The strengths of this study are the contemporary nature of the analysis, using up-to-date data resources, and our

methodologic approach in relation to Spain. However, limitations include a lack of information on confounding variables (e.g., sociocultural attitudes, public health initiatives, economic implications, etc.), which will be unique to each country and cannot be easily extracted or analyzed. The distinction between what constitutes an opt-out versus opt-in country is also blurred. For example, many countries across both systems maintain a register of refusals regardless of the default position, and there are many aspects of hybrid features similar to both systems. Our analysis also relied on data sources voluntarily submitted by relevant countries, with the potential of analyzing misclassified or erroneous data. We have also analyzed the United Kingdom as a single entity, but Wales now differs from the rest of the country because of its switch to opt-out. However, as this was only undertaken on December 1, 2015, the likely impact on 2016 figures extracted for the United Kingdom are likely to be negligible and the Welsh figures are a small contribution to the overall rates. Finally, as with any observational data, association does not automatically imply causality, and we caution against such interpretation of our data. Numerous pitfalls with regards to insufficient control for confounders or selection bias can affect observed associations such as the link between opt-out countries and reduced living donor rates. However, this aligns with our take-home message that the situation on the ground is too complex to simply link opt-out or opt-in directly with organ donation rates or solid organ transplantation activity.

The rationale for undertaking this current analysis is that organ donation and transplantation activity has been subject to numerous confounding interventions, resource investment, and public awareness initiatives to change the climate of organ donation. Therefore, reliance on studies reflecting a bygone era may not truly reflect contemporary donor and transplant activity. Our contrasting findings can therefore be explained by reviewing a number of methodologic differences in relation to previous studies. First,

our analysis is restricted to the most recent year of available data (2016 in most cases, with 5-year analysis of 2012–2016 data) to ensure a contemporary snapshot for organ donation and transplantation activity. This compares with heterogeneous years of focus in previous analyses; for example, Coppen and colleagues⁸ analyzed data from 2000 to 2002, Rithalia *et al.*⁹ analyzed studies with data up to 2008, Horvat and colleagues¹⁰ explored data between 1997 and 2007, and the most recent analysis was between 2000 and 2012 from Shepherd and colleagues.⁶ Analyzing average rates over time also involves different statistical methodology because of variation in rates and activity over time (e.g., multilevel modeling), which limits direct comparison of study data. Previous studies have also chosen their subject countries under analysis using varying rationale (e.g., European countries only, International Registry in Organ Donation and Transplantation–registered countries, OECD countries, or no clear justification for selection). Our justification for using OECD countries in our analysis was the belief that exploring organ donation and transplantation activity is best compared among comparable developed countries with adequate infrastructure and resources. Finally, our primary analysis considered Spain as an opt-in country because of the lack of an official opt-out register, which differs from other analyses, but we did undertake sensitivity analysis with Spain reclassified as opt-out for the sake of completeness with no fundamental change to the results. We believe this is a critical difference that has frequently skewed results to erroneously support opt-out consent as superior for facilitating more organ donation.

Our study findings suggest no significant gain for established opt-in countries considering a switch to opt-out. Although historically some countries have observed impressive increases after introduction of presumed consent, such as Belgium,¹¹ others have fared badly with either no difference or an actual drop in organ donation rates, including Singapore,¹² Brazil,¹³ Chile,¹⁴ Sweden,¹⁵ and more recently Wales.¹⁶ It is important to acknowledge that although actual donation rates have not changed significantly in Wales since the legislation was passed in December 2015,^{17,18} consent for organ donation in Wales is now higher than the rest of the United Kingdom.¹⁹ In fact, Wales is the only country within the United Kingdom to be achieving the target 80% family consent rate for deceased donation set by the UK Strategy “Taking Organ Transplantation to 2020” (<https://www.nhsbt.nhs.uk/tot2020/>). Whether this will eventually lead to improved actual donation rates or can be translated to the rest of the United Kingdom with improved donor–transplantation activity remains uncertain.

Spain is lauded as the exemplar model for a successful deceased organ donation system, which has recently had the accolade of achieving 40 deceased organ donors and 100 transplant procedures per million population, respectively.²⁰ However, as previously highlighted, Spain has no official

opt-out register, and family approval is always sought. With a practically defunct presumed consent system, the lesson from Spain is to emulate their investment in education and infrastructure,²¹ which has been acknowledged by the authors themselves.²² The critical issue, which presumed consent fails to tackle, is the apathetic attitude and behavior among the lay public regarding organ donation. The disconnect between the wish for organ transplantation (if ever required) but simultaneous reluctance to be organ donors (if ever possible) simply will not change with a move to presumed consent. Although a hard version of presumed consent could overcome family objections, the likely backlash¹³ in most established organ donation programs makes this an unattractive option.

Changing attitudes is key, and novel strategies to alter this must be considered. For example, Israel has introduced an organ allocation priority system for registered donors, and early results have shown an impressive increase in both consent rates and actual organ donation.²³ Another possibility is to consider using behavior intervention strategies to improve donor consent,²⁴ bypassing underlying cognitive obstacles with nudge theory to influence decision-making by encouraging positive reinforcement and indirect suggestion.²⁵ Improved use of organs, from reducing deceased donor kidney discard rates²⁶ to increasing use of unconventional or high-risk kidneys,²⁷ may also be more effective strategies to consider bridging the gap between supply and demand. There are many approaches for healthcare providers to consider beyond the simple debate of opt-out versus opt-in, and exploring these unanswered questions with targeted research is key.

To conclude, our data suggest opt-in countries switching to opt-out mechanisms for organ donation are not guaranteed an automatic increase in organ donation rates or solid organ transplantation activity, in keeping with a recently reported opinion piece.⁵ Healthcare providers seeking to increase organ donation would be better served to focus on strategies to overcome cognitive obstacles or apathy to consent in their efforts to encourage more organ donation among the lay public.

METHODS

Country selection

This cross-sectional study used secondary data to compare organ donor and transplant rates among the 35 countries registered with the OECD (www.oecd.org). Organ donation–transplantation rates from the latest available year (2016) were extracted from the Global Observatory for Donation and Transplantation (www.transplant-observatory.org), with any missing data sought from the International Registry in Organ Donation and Transplantation (www.irodat.org). Data from the latest available year were used in most cases (2016 at the time of access).

Stratification of countries into whether their organ donation system was opt-out versus opt-in was made on the basis of published literature and country-specific reports. Broadly speaking, a country was deemed to have an opt-in procurement system if people were considered willing donors if they had registered or declared their

wish to donate as the default position. In contrast, a country was deemed to have an opt-out procurement system if people were considered willing donors if they had not registered an objection to be organ donors as the default position. The use of a formal opt-out register was generally considered a criterion for countries to be classified as having a presumed consent system, but we were also guided by country-specific legislation (Supplementary Table S1). Countries traditionally considered as opt-out (e.g., Spain), which maintains no official opt-out register, were therefore treated as opt-in countries in the initial analysis. However, because this breaks with the traditional approach to handling Spain in analyses of opt-out versus opt-in, we performed additional sensitivity analyses after reclassifying Spain as an opt-out country.

Variables and data sources

Organ donation rates and solid organ transplantation activity per million population was obtained from the Global Observatory for Donation and Transplantation for the following variables: deceased donor rates, living donor rates, deceased kidney transplantation activity, living kidney transplantation activity, total kidney transplantation activity, deceased liver transplantation activity, living liver transplantation activity, heart transplantation activity, lung transplantation activity, pancreas transplantation activity, small bowel transplantation activity, nonkidney transplantation activity, and total solid organ transplantation activity. We obtained socioeconomic variables from the following data sources that were freely available: OECD website, World Health Organization, Pew Research Center, and the UN Department of Economic and Social Affairs. Specific data extracted to be analyzed included country population, gross domestic product (by purchasing power parity), road traffic accidents (total fatalities per 100,000 population), legal system (common vs. civil law, defined as prioritization for published judicial opinions as case laws vs. codified statutes, respectively), main religious denomination, education (percentage in tertiary education system), hospital beds (total per 1000 inhabitant population), government debt (percentage of gross domestic product), household debt (percentage of net disposable income), tax on personal income (percentage of gross domestic product) and health spending (percentage of gross domestic product).

Ethics and transparency

Formal ethical approval was not sought for this study because the analysis was of pre-existing data openly accessible from data repositories. All sourced data are freely available for download by any investigator as required. There is no funding source to declare for this study. The lead author affirms the article is an honest, accurate, and transparent account of the study reported.

Statistical analysis

Univariate comparisons of organ donation rates and transplantation activity were done with χ^2 tests for categorical data and Mann-Whitney U analyses for continuous data. A forward stepwise multiple linear regression analysis was undertaken to investigate the effect of opt-out versus opt-in on organ donation rates or solid organ transplantation activity (continuous dependent variable), adjusted for country-specific economic and social variables (independent variables). Categorical values in the regression model were dummy coded as appropriate. The following variables were included: opt-out versus opt-in, population, gross domestic product, household debt, government debt, tax, road traffic accidents, legal system, religious

affiliation, hospital beds, health spending, and tertiary education. All statistical analysis was performed using SPSS v.24.0 (IBM Corp., Armonk, NY).

DISCLOSURE

All the authors declared no competing interests.

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SUPPLEMENTARY MATERIAL

Table S1. OECD countries in the analysis and detailed breakdown of organ donation legislation.

Supplementary material is linked to the online version of the paper at www.kidney-international.org.

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