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SCIENTIFIC REVIEW

A Systematic Review of Opt-out Versus Opt-in Consent on Deceased Organ Donation and Transplantation (2006–2016)

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Abstract

Background Significant numbers of patients in the USA and UK die while waiting for solid organ transplant. Only 1–2% of deaths are eligible as donors with a fraction of the deceased donating organs. The form of consent to donation may affect the organs available. Forms of consent include: opt-in, mandated choice, opt-out, and organ conscription. Opt-in and opt-out are commonly practiced. A systematic review was conducted to determine the effect of opt-in versus opt-out consent on the deceased donation rate (DDR) and deceased transplantation rate (DTR).
Methods Literature searches of PubMed and EMBASE between 2006 and 2016 were performed. Research studies were selected based on certain inclusion criteria which include USA, UK, and Spain; compare opt-in versus opt-out; primary data analysis; and reported DDR or DTR. Modeled effect on US transplant activity was conducted using public data from Organ Procurement and Transplantation Network and Centers for Disease Control WONDER from 2006 to 2015.
Results A total of 2400 studies were screened and six studies were included. Four studies reported opt-out consent increases DDR by 21–76% over 5–14 years. These studies compared 13–25 opt-out countries versus 9–23 opt-in countries. Three studies reported opt-out consent increases DTR by 38–83% over 11–13 years. These studies compared 22–25 opt-out versus 22–28 opt-in countries. Modeled opt-out activity on the USA resulted in 4753–17,201 additional transplants annually.
Conclusion Opt-out consent increases DDR and DTR and may be useful in decreasing deaths on the waiting list in the USA and other countries.
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An earlier version of this work was orally presented at the American Transplant Congress in 2017 and can be found in [61].

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Introduction

Globally, there is a shortage of donor organs relative to patients waiting for transplantation. Only 1–2% of deaths meet criteria to be considered organ donors [1]. A total of 100 people die weekly in the USA waiting for a transplant [2]. Thus, converting potential donors to actual organ donors is of utmost importance. Chatterjee et al. studied the effect of state policy in the USA on increasing the rate of donation and transplantation. First person consent laws, donor registries, public education programs, paid leave, and tax incentives all had no significant effects on the combined deceased and living donor pool [3]. The only effective policy was state revenue pools for donor recruitment which resulted in an additional 8 organs per state [3]. In America, 15–45% of deceased donations (DDs) are lost during consent [4]. In a 2013 survey, 97.6% of Americans supported organ donation, but only up to 60% registered as donors. Additionally, 15.8% of respondents would not donate their organs [2]. Thus, there is a sizeable population that supports donation, would donate, but has not registered.

The method of consent for donation may affect organ donation rates. There are four methods of organ donation: opt-in, mandated consent, opt-out, and organ conscription [5, 6]. Opt-in or informed consent is defined as optional registration. Mandated consent requires registration of intent to donate or not donate. Opt-out also referred to as presumed consent or deemed consent is defined as default registration as a donor with the option to unregister. Organ conscription is defined as routine procurement of organs without a process of consent.

Opt-out has been considered a potential solution to increasing rates of donation in many countries. In a recent study, 21 of 25 opt-out countries allowed next of kin to prevent donation [7]. This is the structure of the soft opt-out policy implemented in Wales, UK in 2015 and the system used in Spain [8]. Opt-out has also been criticized as a policy that decreased donation in Brazil and Singapore [9–11]. However, retrospective analysis showed positive increase on donation [12–14]. In 2010, Japan did not increase donation as much as expected after implementing a similar model [15]. In this case, results may be confounded by the high rate of living donors. In 2014 in Japan, there was a waiting of list of 376 patients, 400 living donor liver transplants (LDLTs), and 40 deceased donor liver transplants (DDLTs) [16]. In 2013 in America, there was a waiting list of 15,000, 252 LDLTs, and 6203 DDLTs [17].

The Spanish model is often cited due to its high rates of donation and transplantation. Before 1989 Spain functioned with opt-in before changing to an opt-out. In addition to opt-out other changes were made including: a national/regional/hospital coordination network, establishing a transplant coordinator, and approaching family members [18]. Corresponding with these changes, deceased organ donation has more than doubled from 1989 to 1999 from 14.3 DDs per million population (PMP) versus 33.6 DDs PMP [18]. In 2000, Korea also implemented system changes without opt-out consent including: an incentive system, an organ procurement organization, a donor registry, and donor referral system [19]. This increased rates from 1.09 DDs PMP in 2000 to 9.72 DDs PMP in 2015 [19]. Thus, although system changes are important, the impact of opt-out is significant.

The UK has faced similar issues with deaths on the organ waiting list. Individual British physicians and surgeons have debated utility of opt-out consent to improve organ donation [20, 21]. Officially, the British Medical Association (BMA) is in strong support of broad adoption of the opt-out consent [22, 23]. In 2013, Wales, UK, passed the Human Transplantation (Wales) Act, which authorized the use of soft opt-out or deemed consent beginning in December of 2015 [8, 24]. Transplants in Wales increased by approximately 20% during 2015–2016 [25]. In 2015–2016 Donation after Brainstem Death (DBD) donors were consented at rates of 68.7% with opt-in and 100% with opt-out [26]. The UK is currently evaluating legislation which may make opt-out nationalized by 2020 [27].

The utility of opt-out consent relies on the idea that there are eligible donors that are being unrealized due to issues with consent. The Institute of Medicine reported that addressing consent for unexpected deaths in US would add 22,000 additional donors every year [28, 29]. In the USA, opt-out consent has not been seriously considered as a solution for organ supply due to a lack of evidence [30–32]. This systematic review focuses on literature published from 2006 to 2016 which was not covered by a previous systematic review [33, 34]. In addition, our projection and analysis includes a novel measure of efficiency to benchmark donation yield and a measure for transplant effectiveness in the USA and globally: DD per 10,000 deaths (DD per 10KD) and Transplants/Active Waiting List.

Materials and methods

Search strategy

The literature was searched systematically from January 1, 2006, to November 6, 2016. The PubMed and Embase databases were selected, and a synonym table was created to develop a comprehensive and focused search strategy. The search criteria included articles in English, published from 2006 to 2016 and key words. See "Appendix" for complete search. This systematic review is registered as PROSPERO CRD42019098759.

Selection of studies

Titles, abstracts, and full publications were assessed independently by two reviewers. A total of 2400 results were returned after duplicates were removed. Inclusion criteria for each study was as follows: (1) It must have a primary data analysis comparing opt-in to opt-out consent policy; (2) it must contain data from USA, UK, and Spain; (3) it must contain endpoint of deceased donation rate (DDR) OR deceased transplantation rate (DTR). Titles and abstracts were screened to exclude studies that were not relevant to the topic. The resulting articles were discussed by the two reviewers for agreement on inclusion. Disagreements or unclear issues were referred to a third reviewer for clarification.

Risk of bias

The resulting publications were reviewed for risk of bias by two reviewers. Scores were independently generated and averaged for a final rating of each study. Risk of bias was assessed using the Downs and Black criteria [35].

Statistical analysis

A planned meta-analysis could not be performed due to heterogeneity of studies. The range of effect on deceased donation rate (DDR) within our systematic review was used to determine an estimate for a potential increase in the donation and transplantation rate in the USA. The publicly available data from United Network for Organ Sharing (UNOS) database was accessed for 11 years of data on donors, transplants, and deaths on the waiting list for 52 states and territories in the USA from 2005 to 2015 [36]. The publicly accessible Centers for Disease Control (CDC) WONDER database was accessed for data on total deaths and population by state and year for the same time period [37]. The upper limit of deceased donor potential was estimated at 1.5% of total deaths as a ratio of deceased donor potential/total deaths as determined in Klassen et al. [1].

US national level projection was constructed using the following assumptions. Waiting list, DDs, deceased transplants (DTs), and waiting deaths was extracted from the UNOS database. Population and mortality was extracted from the CDC WONDER database. A trendline was generated with Microsoft Excel for waiting list, DDs, population, and waiting deaths to optimize R^2 (0.80–0.99). These measures were projected forward to 2020 using the calculated line equations. Conversion of DDs to DTs was calculated by the ratio of total DTs/total DDs from 2005 to 2015.

State level data for DDs per 10KD was reported as a mean value of 10 years of data from 2006 to 2015 as a simple ratio from the UNOS database and CDC WONDER database. Regional increases in transplant activity were calculated using the following method. A mean value of donors and transplants was calculated for each region from the Organ Procurement and Transplantation Network (OPTN) database from 2006 to 2015. The DDs were modified by the range of effect by opt-out, 21–76%. The ratio of DTs/DDs was recalculated regionally and used to generate potential DTs based on opt-out.

Global comparison of two measurements of transplant and donation activity were calculated and charted for 15 opt-in and 21 opt-out countries using DD, transplant, and waiting list data from the 2017 European Directorate for the Quality of Medicines (EDQM) report and mortality data from the World Bank [38, 39]. Two measurements were calculated: (1) transplants/active waiting list (2) DD per 10KD. US performance was also estimated at three levels of effect with opt-out.

Results

Search results

A total of 2945 records were identified through search methods. After duplicates were removed the final number of studies was 2400. The titles of these records were screened, and 2,250 were excluded based on topic. In total, 150 abstracts or truncated texts of articles were reviewed and assessed for eligibility with 128 excluded. Twenty-two full text articles were assessed for eligibility with only five articles meeting inclusion criteria. An additional article was referenced in several publications and was only found as an abstract in our search methodology. This was added to the final articles reviewed. The PRISMA flowchart depicts the eligibility criteria for studies to be included in Fig. 1.

Study characteristics

The characteristics extracted include author, year of publication, study design, number of opt-out and opt-in countries, years of data analyzed, types of organs, statistical significance, outcome measures, change in outcome measures, other significant variables with positive or negative effects on deceased donation, and the effect of opt-out

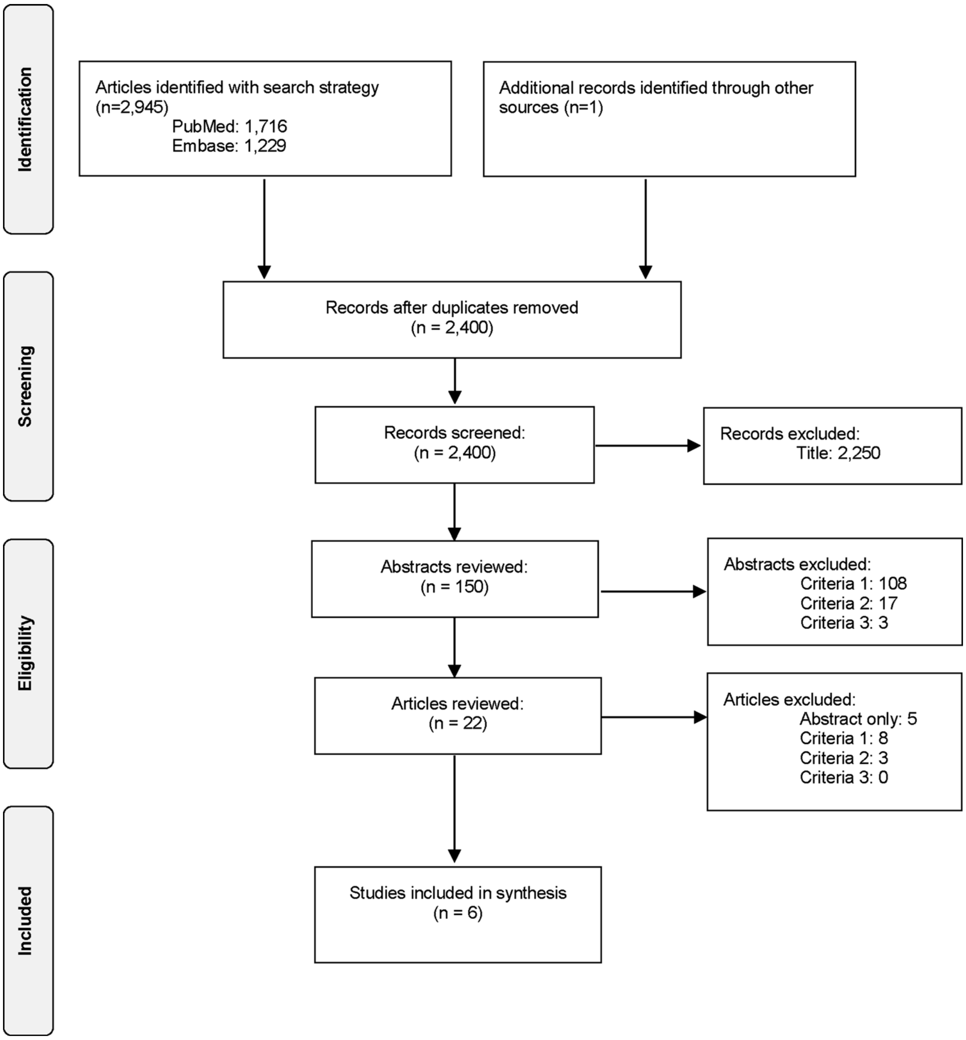

Fig. 1 PRISMA flow diagram and selection process for studies Moher D, Liberati A, Tetzlaff J, et al. (2009) PRISMA 2009 Flow Diagram. PLoS Med. https://doi.org/10.1371/journal.pmed1000097

on living donation [12, 40–44]. Results from each study are abstracted in Table 1.

Risk of bias within studies

Risk of bias was assessed and summarized using the Downs and Black tool [35] in Table 2. Each domain was scored with a value of 1 for good quality, 0 for bad quality, and non-applicable domains received a value of 1. In the reporting domain, an assessment of confounding variables is scored with a value of 2 for yes, 1 for partial list, and 0 for no. Using Downs and Black, the six studies had a median (range) of 26 (25–27).

Effect of opt-out consent

All six studies showed that opt-out consent increased DDR or DTR [12, 40–44]. Three studies focused on all solid organs and reported DDR as the main outcome [12, 40, 41]. One study reported results for kidney, liver, heart, and lung transplants and reported DDR and DTR as the main outcomes [42]. Two studies focused solely on kidneys and reported DTR as the main outcome [43, 44]. Living donor kidney transplants were decreased in the opt-out model compared to opt-in [42–44]. However, when comparing the total number of transplants opt-out was greater than opt-in [42]. Four studies reported opt-out consent increased the DDR within a range of 21–76% for opt-out versus opt-in over study periods of 5–14 years [12, 40–42]. These studies compared 13–25 opt-out countries versus 9–23 opt-in countries. Three studies reported opt-out consent increased the DTR within a range of 38–83% for opt-out versus opt-in over study periods of 11–13 years [42–44].

Table 1 Summary of results

Author, Year	Study design	(Opt-out/ Opt-in)	Years	Organ	Significance	Outcome	Change	Other Variables	Liv Don[a]
Bilgel, 2012[b]	Fixed effects vector decomposition	(15/9)	1993–2006	ALL	Yes	DDR PMP	+ 26-76%	+ HCE, + PD, + LIB, + CL, + FC, + CR	NA
Neto, 2007	Quantile regression for longitudinal data	(20/14)	1998–2002	ALL	Yes	DDR PMP	+ 21–26%	+ GDP, + HCE, + PD, ± CRG, + CL	NA
Abadie, 2006	Logistic regression	(13/9)	1993–2002	ALL	Yes	DDR PMP	+ 31%	+ GDP, + HCE, + CL, + PD	NA
						w/o Spain	+ 25%		
Shepherd, 2014	Multi-level modeling (MLM)	(25/23)	2000–2012	KD, LV, HT, LU	Yes	DDR PMP	+ 42.7%	+ Y, + GDP, ± CRG, -HB	-
						w/o Spain	+ 35.9%		
				KD, LV, HT, LU	Yes, Yes	DTR PMP	+ 62%, + 61%	+ Y, + GDP, ± CRG, -HB	-, -
					No, No		+ 38%, + 54%		NA
Bendorf, 2013	Univariate/Multivariate analysis	(25/28)	N/A	KD	Yes	DTR PMP	+ 83%	+ NDDP, + GDP, + HCE, + EDE, ± GR, ± RG, + A > 80	-
Horvat, 2010	Longitudinal study	(22/22)	1997–2007	KD	Yes	DTR PMP	+ 63%	+ GDP, + HCE, + PS	-

DDR deceased donation rate; *DTR* deceased transplantation rate, *PMP* per million population; *HCE* health care expenditure; *PD* potential donors; *LIB* civil liberties; *CL* common law; *FC* family consent; *CR* combined registry; *NA* not applicable; *GDP* gross domestic product; *CRG* catholic religion; *KD* kidney; *LV* liver; *H* heart; *LU* lung; *Y* year; *HB* hospital beds; *NDDP* national deceased donor program; *EDE* educational expenditure; *GR* global region; *RG* religion; *A* age; *PS* Physician supply

[a] Effect on living donation

[b] Model 6 includes all significant variables and interaction effects and these results are shown

Table 2 Downs and Black criteria for non-randomized studies (1998)

Author, Year	Reporting (10)	External validity (3)	Internal validity bias (7)	Internal validity confounding (6)	Sufficiently powered?	Total score
Bilgel, 2012	10	3	6	6	1	26
Neto, 2007	11	3	6	6	1	27
Abadie, 2006	11	3	6	6	1	27
Shepherd, 2014	10	3	6	6	1	26
Bendorf, 2013	11	3	6	5	1	26
Horvat, 2010	10	3	6	6	0	25

These studies compared 22–25 opt-out versus 22–18 opt-in countries.

Effects of other variables

Bendorf et al. showed that a national deceased donor program had the single largest effect on DTR [44]. Healthcare expenditure (HCE), gross domestic product (GDP), potential donors (PD), common law (CL), civil liberties (LIB), family consent (FC), a combined registry (CR), education expenditure (EDE), increased age, and physician supply (PS) were positively correlated with deceased donation or transplantation [12, 40–44]. Due to differences in calculation of metrics used and analytic methods, it is difficult to directly compare the magnitude of impact of other variables studied on DTR and DDR. Bilgel found the relative impact of variables on donation were as follows HCE > PD > opt-out [40]. Neto found the relative impact of variables on donation were as follows GDP > opt-out > PD > CL > CRG [12]. Abadie found the relative impact of variables on donation were as follows PD > CL > opt-out > GDP [41]. Shepherd accounted for the effect of national variables in their analytic method but the relative impact of other variables was not clear as it was not the part of their study aims [42]. Bendorf found that opt-out > GDP in their multivariate analysis [44]. Horvat did not conduct a multivariate analysis, and thus the relative impact of variables is less clear than the methods used in other studies but GDP, HCE, and PS all had a positive effect on donation rates [43]. Religion had inconsistent correlation with organ donation [12, 40, 42, 44].

Additional analyses

From 2006–2015, US performance with the average annualized metric of DD per 10 KD was > 50 under current opt-in consent for the District of Columbia, Kansas, Utah, Delaware, Alaska, and Pennsylvania (Fig. 2). The DTR was modeled using annualized DDs from 2006–2015 for each UNOS region and the range of effect of opt-out versus opt-in based on the systematic review. The resulting potential increase in average annual transplants ranged from 4753 to 17,201 (Fig. 2). Projecting the effect of opt-out nationally to 2020, the median effect on deceased donation may have the potential to reduce the deaths on the waiting list (Fig. 2). A global scatter plot of performance comparing opt-out and opt-in countries for the year 2016 shows that some countries are performing at higher levels of transplants/active waiting list at much lower rates of DD per 10 KD (Fig. 3).

Discussion

This systematic review summarizes evidence of the effect of opt-out versus opt-in on DDR and DTR. Overall, the evidence suggests opt-out versus opt-in policy increases the DDR and DTR. Other factors may also affect organ supply such as HCE, GDP, PD, CL, LIB, FC, CR, EDE, increased age, and PS [12, 40–44]. The metric of DD per 10 KD was designed based on the significance of potential donors across studies. The metric of Transplants/Active Waiting List was designed to assess the ability of the transplant system to meet the demand for organ transplantation.

Several ethical concerns have arisen in the ongoing debate regarding opt-out and opt-in consent. The main arguments seem to surround two topics: (1) autonomy and a patient's right of choice and (2) the role of the family or next of kin in decision-making.

Some critics discuss an infringement of patient autonomy by arguing the opting out requires understanding the law and the ability to access and perform the opt-out option [45]. Others counterargue that the opt-out consent process would not undermine an individual's autonomy because it should be simple to educate the population and institutionalize an opportunity to opt-out [25, 46]. Public

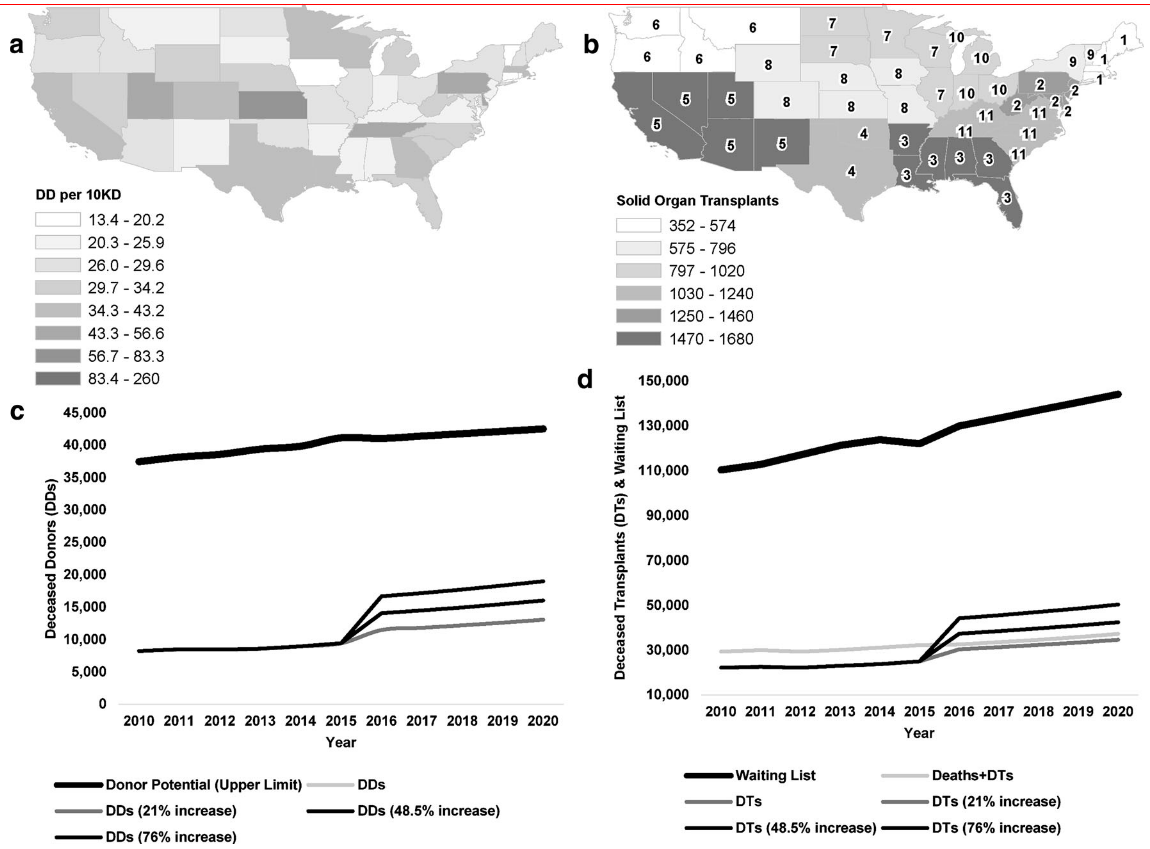

Fig. 2 Projection and analysis of donor potential, deceased donors (DDs), deceased transplants (DTs) by state and total USA **a** Rate of deceased donors per 10,000 deaths (DDs per 10 KD) are shown by state as an annualized mean value. States and territories (region) included in this estimate but not depicted include Alaska (6), Hawaii (6), and Puerto Rico (3). Image created using ArcGIS Desktop 10.5.0.6491. **b** Annualized, mean increased transplants with opt-out consent are shown by UNOS/OPTN region. Calculations were based on the median value for increase of DDs with opt-out consent, 48.5%. The total number of increased solid organ transplants at this level across the USA was calculated at 10,997. Four states (Alaska, Idaho, Montana, and Wyoming) did not have any transplant activity, and thus the data are depicted regionally. This was due to difficulty ascertaining organ destination. States and territories (region) included in this estimate but not depicted include Alaska (6), Hawaii (6), and Puerto Rico (3). Image created using ArcGIS Desktop 10.5.0.6491. **c** Deceased donor potential and deceased donation were forecasted. The upper limit of deceased donation potential is based on the ratio of deceased donors to total mortality from Klassen et al. Three levels of opt-out effect are calculated as a potential change in deceased donation. Image created using Microsoft Excel Version 1803. **d** Waiting list, deceased transplants (DTs), and DTs plus deaths were forecasted till 2020 with the potential effect of opt-out consent at three levels. Deaths on the waiting list is the difference between Deaths + DTs and any DTs line. Image created using Microsoft Excel Version 1803. Klassen DK, Edwards LB, Stewart DE, et al. (2016) The OPTN Deceased Donor Potential Study: Implications for Policy and Practice. Am J Transplant 16:1707–1714

education may be a confounding variable. When evaluating this factor, opt-out versus opt-in countries showed a higher willingness to donate organs with public education [47].

Other critics argue opt-out consent may limit the patient's ability to make an informed choice [48]. Scholars have focused on analyzing the specific language in the codification of these laws. Veatch and Pitt critically analyzed existing opt-out laws and argued opt-out can only be implemented in a scenario where public support of organ donation is at a figure greater than 95%, which is supported by public survey data from 2013 [2, 45].

Bilgel's results showing the success of opt-out were reliant on the family's role in the process of consent [40]. Thus, despite little difference between opt-out and opt-in systems in terms of family involvement, the opt-out systems seem to have higher donation rates. Rodrigue et al. showed 15.5% of registered donors were refused as donors by families or next of kin [49]. However, based on recent evidence from the UK, policy makers believe this would be reduced with opt-out consent [26].

Critics of opt-out have valid concerns as illustrated by the cases of Brazil and Singapore. Brazil's problems could have been avoided by addressing the health system, public

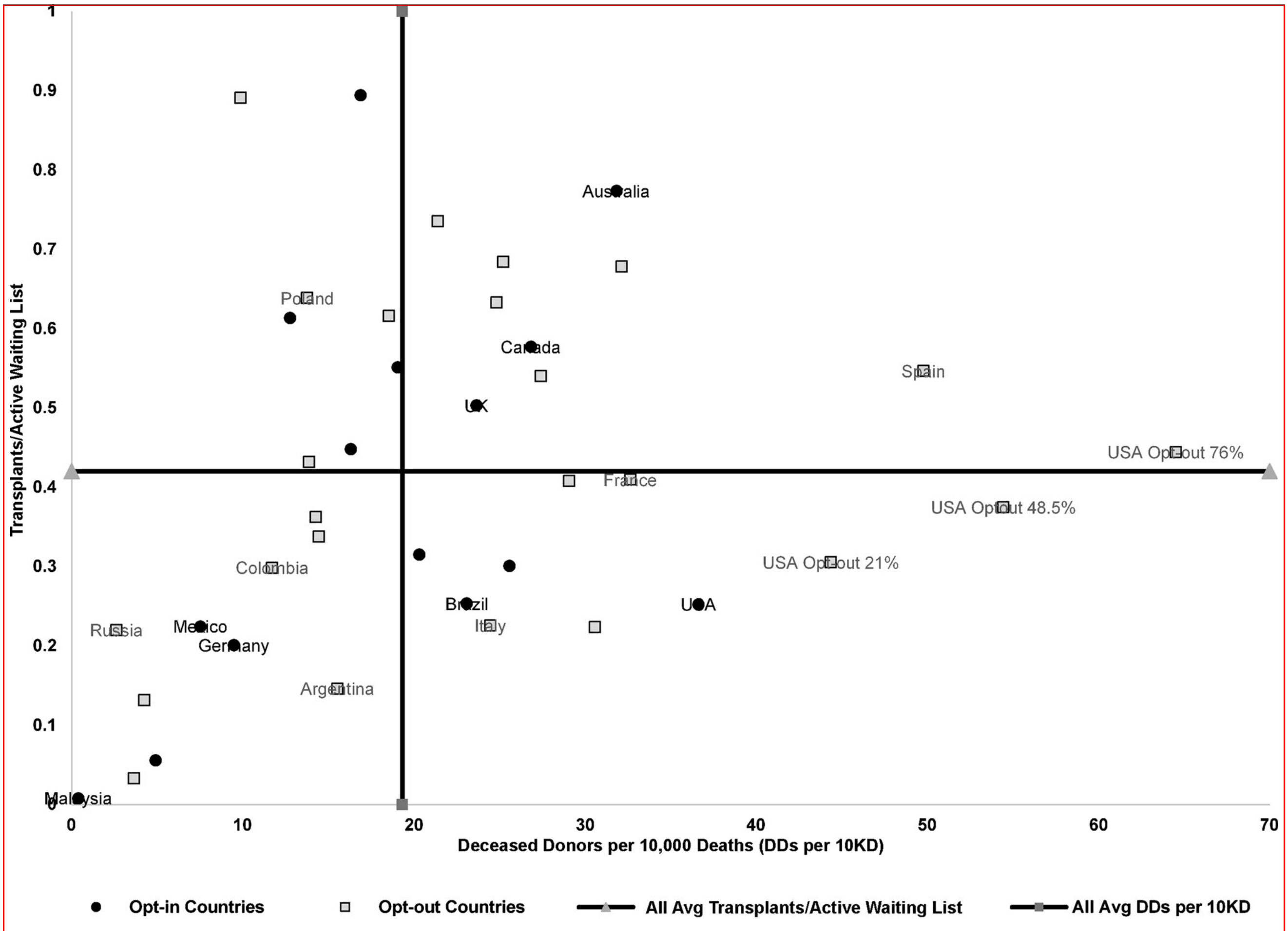

Fig. 3 2016 Transplants/active waiting list and deceased donors per 10,000 deaths (DDs per 10 KD) for 15 opt-in and 21 opt-out countries. DD, transplant, and waiting list data from the 2017 European Directorate for the Quality of Medicines (EDQM) report and publicly available mortality data from the World Bank web site. Two measurements were calculated: (1) transplants/active waiting list (2) DD per 10 KD. US performance was also estimated at three levels of effect with opt-out. Domínguez-Gil B, Mahillo B, Alvarez M, et al. (2017) Newsletter Transplant International figures on donation and transplantation 2016. Eur Dir Qual Med Healthc Counc Eur

and professional education, and family consent. In February 1997, Brazil passed law 9434 which was a version of opt-out consent for organ donation without family consent [50]. This law encountered difficulty due to limited critical care beds per capita and inadequate donor management for projected growth [51–54]. These issues were rectified after the law was passed with the number of critical care hospitals increasing from 12 to 36 over six years in Rio Grande do Sul [55, 56]. The law was not well understood by the public, health professionals, and religious leadership [57–59]. Although data now shows an increase from 2.6 to 4.1 DDR PMP between 1997 and 1998, at the time opt-out was thought to have had decreased donation in Brazil due to media coverage, discourse, and inadequate data reporting [9, 12]. As a result, opt-out was changed to opt-in in 2001 and family consent was reintroduced [60]. Similarly, since 1987, opt-out compared to opt-in nearly doubled the rate of donation in Singapore and increased deceased donor liver transplants [13, 14]. However, relative to other countries this was below expected results and advocates for organ donation point to issues in the health system, local culture, and religious belief for the current rate [10, 11].

Limitations

Three studies with the endpoints of DDR or DTR were excluded due to not including the USA, UK, or Spain. The range of modeling on the potential effect on US transplant activity is broad and median values should be considered. None of the reviewed studies were prospective, randomized controlled trials. Thus, the results of this systematic review must be taken with caution.

Conclusion

The organ shortage problem is of great interest to patients, health care providers and policy makers. Although there are many potential solutions for increasing the organ supply and rate of transplantation, opt-out consent policy has shown a recent resurgence in interest. In literature, six recent studies support the independent effect of opt-out policy on increasing the DDR and DTR. Assuming the policy change is effective, future research should be focused on public education, public opinion, and clarifying the role of family consent in the opt-out consent model. Future research may also benefit from assessing donor yield with a more direct measure such as DD per 10 KD to account for the rate of mortality which may differ greatly.

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Compliance with ethical standards

Conflict of interest The authors declared that they have no conflict of interest.

Appendix

Pubmed and Embase search terms

Embase

Limits activated: English.

((’organ’/exp OR organ) AND donation OR ((’organ’/exp OR organ) AND donations) OR ((’organ’/exp OR organ) AND procurement) OR ((’organ’/exp OR organ) AND procurements) OR ’donation after circulatory death’/exp OR ’donation after circulatory death’ OR (donation AND after AND circulatory AND (’death’/exp OR death)) OR ’donation after brain death’/exp OR ’donation after brain death’ OR (donation AND after AND (’brain’/exp OR brain) AND (’death’/exp OR death)) OR dcd OR dbd OR (posthumous AND (’organ’/exp OR organ) AND procurement) OR (posthumous AND (’organ’/exp OR organ) AND donation) OR ((’organ’/exp OR organ) AND (’transplant’/exp OR transplant))) AND (’explicit consent’ OR (explicit AND consent) OR ’voluntary consent’ OR (voluntary AND consent) OR ’informed consent’/exp OR ’informed consent’ OR (informed AND consent)) AND [2006-2016]/py

AND

((’organ’/exp OR organ) AND donation OR ((’organ’/exp OR organ) AND donations) OR ((’organ’/exp OR organ) AND procurement) OR ((’organ’/exp OR organ) AND procurements) OR (donation AND after AND circulatory AND (’death’/exp OR death)) OR (donation AND after AND (’brain’/exp OR brain) AND (’death’/exp OR death)) OR dcd OR (posthumous AND (’organ’/exp OR organ) AND donation) OR (posthumous AND (’organ’/exp OR organ) AND procurement) OR ((’organ’/exp OR organ) AND (’transplant’/exp OR transplant))) AND ((((presumed AND consent OR pcs OR opt) AND out OR presuming) AND consent OR implicit) AND consent OR deemed) AND consent AND [english]/lim AND [2006-2016]/py

Similar searches were performed in Pubmed.

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